

PenCLAHRC Question Prioritisation 2016/17

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As before, when considering the question, we ask you to think about the PenCLAHRC criteria for research prioritisation:

- The size of the health problem
- The potential for health improvement from answering the research question
- The practicality of answering the research question
- Whether the South West is a good place to do this research
- Alignment with local healthcare priorities

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The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days. The briefing is in four parts:

- i. General context
- ii. The question in a research format
- iii. What the research evidence says
- iv. Alignment with PenCLAHRC research priority criteria

QUESTION: Would a mindfulness approach help reduce medication in patients with chronic pain dependant on opioids?

General context and definitions: *Opioids* refer to opiates (opium, morphine, heroin) as well as semi-synthetic and synthetic opioids such as hydrocodone, oxycodone, methadone, fentanyl and codeine. Opioids are most often used medically to relieve pain. *Chronic pain* is defined as pain that ‘lasts a long time’, often determined by an arbitrary interval of time since onset; the two most commonly used being 3 months and 6 months. Common causes of chronic pain include low back pain, arthritis, fibromyalgia, headache, musculoskeletal pain and neuropathic pain. Chronic pain has a considerable detrimental impact on quality of life, resulting in significant suffering and disability.

Opioids are used to treat moderate to severe chronic pain that may not respond well to other pain medications. Opioid use in chronic pain treatment is complex, as patients may derive both benefit and harm. The major concern is the risk of opioid dependence, addiction and overdose. It has been estimated that more than 10% of chronic pain patients engage in opioid misuse behaviours, such as dose escalation or self-medication of negative emotions. Identification of individuals currently using opioids in a problematic way, and treating this misuse, is important given the substantial recent increases in prescription rates and related increases in morbidity and mortality.

Mindfulness is the process of bringing one's attention to the internal and external experiences occurring in the present moment which can be developed through the practice of meditation and other training.

The question in a structured format: In considering this as a research question, we could frame it as:

<i>Population:</i>	Adults with chronic pain, dependent on opioids (such as oxycodone)
<i>Intervention:</i>	Mindfulness therapy
<i>Comparator:</i>	No mindfulness/ Usual care
<i>Outcomes of Interest:</i>	Use of opioid medication Pain, Physical health (spasms, tremors, condition specific outcomes), Functional ability, Quality of life Adverse effects of therapy

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What the research evidence says: There have been a number of systematic reviews in the past five years assessing the effectiveness of mindfulness therapy for chronic pain, though none have specifically targeted whether mindfulness therapy can assist in opioid withdrawal.

Hilton et al [1] assessed the effectiveness of mindfulness meditation for adults with chronic pain. From 36 included studies, the authors concluded that mindfulness meditation was associated with statistically significant improvements in depression, physical health-related quality of life, and mental health-related quality of life. Only four studies reported the effects on pain medication: two found no reduction in use, one found a significant reduction in opioid use, and one a reduction in those misusing opioids. Bawa et al [2] assessed the effectiveness of mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT) for patients with chronic pain. From eleven studies, the authors found limited evidence for the effectiveness of mindfulness-based interventions for patients with chronic pain. The impact on pain medication was not reported as an outcome in the review. Song et al [3] reviewed the effectiveness of mindfulness intervention for adults with chronic pain and psychological comorbidity. From eight trials, the authors concluded that mindfulness therapy improves depression and trait anxiety, but no effects on medication were reported.

Eilender et al [4] in their narrative review of opioid disorder and chronic pain found only two studies that had assessed the value of mindfulness and cognitive behavioural therapy. The authors concluded that while promising results were observed for mindfulness and cognitive behavioural therapy for helping patients with opioid misuse and chronic pain, the evidence was limited by the small size and design of the studies.

A few primary research studies have been published in this area. Zgierska et al [5] describe a small-scale feasibility and acceptability randomised controlled trial of mindfulness meditation for individuals with chronic low back pain on long term daily opioid therapy. The 26 week intervention was found to be acceptable, feasible and safe. The percentage of participants treated with more than 200 mg of Morphine Equivalent Dose per day decreased slightly in the experimental (from 28.6% to 20.0%) but not control (from 21.4% to 23.1%) group by 26 weeks, but the authors noted this was primarily a feasibility trial, and further research (with a larger sample size) to assess effectiveness is required. Gardiner et al [6] describe a pilot study of 'Integrative Medicine Group Visits' for underserved communities with chronic pain and depression. The intervention combines MBSR with self-care management and acupuncture. The eight week pilot study reported reductions in pain and a reduction in the number at risk of opioid misuse. Garland et al [7] report on a randomised controlled trial assessing the feasibility and efficacy of a 'Mindfulness Orientated Recovery Enhancement' (MORE) program. MORE is a multimodal intervention that integrates mindfulness training, cognitive reappraisal skills, and positive emotion regulation into a therapeutic approach designed to modify the feedback loop between chronic pain, habit behaviour, craving and opioid misuse behaviour. Chronic pain patients (n=115) on long term opioids were randomised to eight weeks of MORE or a support group. After eight weeks, participants in the MORE group reported less pain, less desire for opioids and were significantly more likely to no longer meet the criteria for opioid use disorder.

Ongoing studies/ Trials in progress Several protocols for systematic review in this area have been registered in the past two years. A '*Comparative evaluation of mindfulness-based stress reduction and cognitive-behavioural therapy for the treatment and management of chronic pain disorders: a systematic review and meta-analysis protocol*' was registered in 2014 on the PROSPERO register of systematic review protocols, however there has been no publication of any findings to date. Further

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protocols on this register were found for reviews of mindfulness as sole therapy for chronic pain (2015), and as adjuvant therapy in the treatment of headache (2016). A Cochrane protocol on '*Mindfulness based interventions for substance use disorders (including prescription drugs)*' was registered in 2015. No full review has as yet been published.

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: Chronic pain has been estimated to affect between one-third and one-half of the population of the UK [8]. Prevalence rates of chronic pain for Europe range from 12 to 30% [9]. Chronic pain has recently been highlighted as one of the most prominent causes of disability worldwide by the Global Burden of Disease reviews [10]. National governments have started to recognise that chronic pain represents a major priority and challenge for their public health and healthcare systems through production of national strategies and convening of 'Pain Summits' in countries including the UK, the USA and Australia [8]. Opioid prescribing in the UK adult population almost doubled for weaker opioids over 2005-2012 and rose over six-fold for stronger opioids [11]. In addition, accumulating evidence supports the increased risk for serious harms associated with long-term opioid therapy, including overdose, opioid abuse, fractures, and myocardial infarction; for some harms, the risk seems to be dose-dependent (Chou 2016).

The potential for health improvement: Chronic pain is one of the most common conditions encountered by healthcare professionals, particularly among older (≥ 65 years) patients. Long-term opioid dependence for pain management is also highest among older female adults [11, 12]. Interventions that are able to help individuals with chronic pain reduce their dependence are likely to have significant health impact.

The practicality of the research question: Mindfulness as a therapy for treating chronic pain has a small but growing evidence base, and there is increasing interest in non-pharmacological approaches to treating chronic pain. The research question appears practical, given that initial research findings with adults (albeit from small pilot studies) suggest it is feasible, safe and acceptable as an adjuvant treatment for populations with chronic pain and opioid dependence. Researchers have recognised that there needs to be larger more robust studies designed to assess its effectiveness and whether it can help reduce opioid medication.

Whether the South West is a good place to do this research: Mindfulness has been an important part of the University of Exeter since 2004 and work there involves training, research and clinical practice. In the South West there is expertise in training mindfulness practitioners, including at the University of Exeter and Mindfulness Cornwall. Chronic pain is one of the most common conditions encountered by healthcare professionals, particularly among older (≥ 65 years) patients. In terms of population, in 2013 the Office for National Statistics reported that the South West was the region with the highest proportion of older people.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

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GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

Scottish Intercollegiate Guidelines Network (SIGN). Management of chronic pain. Edinburgh: SIGN; 2013. (SIGN publication no. 136). [December 2013]. Available from URL: <http://www.sign.ac.uk/pdf/SIGN136.pdf>

- Found the evidence was currently insufficient to recommend mindfulness for chronic pain

Centers for Disease Control and Prevention (CDC). CDC Guideline for Prescribing Opioids for Chronic Pain- United States, 2016. Available from: <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

The key recommendations from the CDC for primary care physicians treating patients for pain not due to cancer or end-of-life conditions include the following:

- Non-pharmacologic and non-opioid pharmacologic pain management therapies are preferred for chronic pain management.
- Opioids should be used only if expected benefits in pain reduction and improved functioning outweigh the risks. Opioids should be continued only if clinically significant benefits are achieved that outweigh the risks.

The British Pain Society. 2010. Opioids for persistent pain: Good practice. *A consensus statement prepared on behalf of the British Pain Society, the Faculty of Pain Medicine of the Royal College of Anaesthetists, the Royal College of General Practitioners and the Faculty of Addictions of the Royal College of Psychiatrists*

Relevant Abstracts:

Mindfulness-oriented recovery enhancement for chronic pain and prescription opioid misuse: results from an early-stage randomized controlled trial. 2014 Garland EL, Manusov EG, Froeliger B, Kelly A, Williams JM, Howard MO. *J Consult Clin Psychol.* 2014 Jun;82(3):448-59. doi: 10.1037/a0035798. Epub 2014 Feb 3.

OBJECTIVE: Opioid pharmacotherapy is now the leading treatment for chronic pain, a problem that affects nearly one third of the U.S. population. Given the dramatic rise in prescription opioid misuse and opioid-related mortality, novel behavioral interventions are needed. The purpose of this study was to conduct an early-stage randomized controlled trial of Mindfulness-Oriented Recovery Enhancement (MORE), a multimodal intervention designed to simultaneously target mechanisms underpinning chronic pain and opioid misuse.

METHOD: Chronic pain patients (N = 115; mean age = 48 ± 14 years; 68% female) were randomized to 8 weeks of MORE or a support group (SG). Outcomes were measured at pre- and posttreatment, and at 3-month follow-up. The Brief Pain Inventory was used to assess changes in pain severity and interference. Changes in opioid use disorder status were measured by the Current Opioid Misuse Measure. Desire for opioids, stress, nonreactivity, reinterpretation of pain sensations, and reappraisal were also evaluated.

RESULTS: MORE participants reported significantly greater reductions in pain severity (p = .038) and interference (p = .003) than SG participants, which were maintained by 3-month follow-up and mediated by increased nonreactivity and reinterpretation of pain sensations. Compared with SG participants, participants in MORE evidenced significantly less stress arousal (p = .034) and desire for opioids (p = .027), and were

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significantly more likely to no longer meet criteria for opioid use disorder immediately following treatment ($p = .05$); however, these effects were not sustained at follow-up.

CONCLUSIONS: Findings demonstrate preliminary feasibility and efficacy of MORE as a treatment for co-occurring prescription opioid misuse and chronic pain.

Integrative medical group visits: A pilot study to manage patients with comorbid chronic pain and depression. 2016 P. Gardiner, L. Negash, K. G. Barnett, L. F. White, D. Crooks, S. Stillman, A. S. Lestoquoy, C. Farrell-Riley and P. Adelstein. *Journal of Alternative and Complementary Medicine* 22 (6)

Purpose: This pilot study evaluated a 9 week Integrative Medical Group Visit (IMGV) program for patients with chronic pain and depression. The objective of the IMGV was to combine Mindfulness- Based Stress Reduction (MBSR) and Evidence-Based Integrative Medicine techniques with a group medical visit to reduce pain and depressive symptoms. Methods: Patients completed questionnaires at baseline and at 9 weeks. Outcome measures included the Pain Self-Efficacy Questionnaire (PSEQ) and the Patient Health Questionnaire (PHQ-9) to assess depressive symptoms. Exploratory outcomes included Functional Social Support (FSS), Perceived Stress Scale (PSS), Patient Activation (PAM) and Current Opioid Misuse Measure (COMM). These continuous outcome measures were analyzed using two-sample t-tests. Results: Twenty-one patients were enrolled in group visits between December 2014 and January 2015. Among participants, 50% were Black and 15% Latino/a; the majority were low-income. Preliminary analyses of change between baseline and 9 week data show that participants had an average increase in pain self-efficacy of 7.36 ($p = 0.10$) and an average decrease in PHQ-9 score of 4.29 ($p = 0.02$). Analyses of the remaining outcome measures shows an increase in social support ($p = 0.03$ FSS), a decrease in perceived stress ($p = 0.05$ PSS), an increase in patient activation ($p = 0.001$ PAM), and a decrease in the risk of opioid abuse 5.14 ($p = 0.01$ COMM). Conclusion: In a pilot study, the IMGV program reduced depression and increased pain self-efficacy. Preliminary data is promising for other exploratory outcomes as well, especially for increased patient activation. The IMGV model for care should be explored further.

Mindfulness Meditation-Based Intervention Is Feasible, Acceptable, and Safe for Chronic Low Back Pain Requiring Long-Term Daily Opioid Therapy. 2015 Zgierska AE, Burzinski CA, Cox J, Kloke J, Singles J, Mirgain S, Stegner A, Cook DB, Bačkonja M. *J Altern Complement Med.* 2016 Aug; 22(8):610-20. doi: 10.1089/acm.2015.0314. Epub 2016 Jun 7.

OBJECTIVE: Although mindfulness meditation (MM) is increasingly used for chronic pain treatment, limited evidence supports its clinical application for opioid-treated chronic low back pain (CLBP). The goal of this study was to determine feasibility, acceptability, and safety of an MM-based intervention in patients with CLBP requiring daily opioid therapy.

DESIGN: 26-week pilot randomized controlled trial comparing MM-based intervention, combined with usual care, to usual care alone.

SETTING: Outpatient.

PATIENTS: Adults with CLBP treated with ≥ 30 mg of morphine-equivalent dose (MED) per day for 3 months or longer.

INTERVENTIONS: Targeted MM-based intervention consisted of eight weekly 2-hour group sessions and home practice (30 minutes/d, 6 days/wk) during the study. "Usual care" for opioid-treated CLBP was provided to participants by their regular clinicians.

OUTCOME MEASURES: Feasibility and acceptability of the MM intervention were assessed by adherence to intervention protocol and treatment satisfaction among experimental participants. Safety was evaluated by inquiry about side effects/adverse events and opioid dose among all study participants.

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RESULTS: Thirty-five participants enrolled during the 10-week recruitment period. The mean age (\pm standard deviation) was 51.8 ± 9.7 years; the patients were predominantly female, with substantial CLBP-related pain and disability, and treated with 148.3 ± 129.2 mg of MED per day. All participants completed baseline assessments; none missed both follow-up assessments or withdrew. Among experimental participants ($n = 21$), 19 attended 1 or more intervention sessions and 14 attended 4 or more. They reported, on average, 164.0 ± 122.1 minutes of formal practice per week during the 26-week study and 103.5 ± 111.5 minutes of brief, informal practice per week. Seventeen patients evaluated the intervention, indicating satisfaction; their qualitative responses described the course as useful for pain management ($n = 10$) and for improving pain coping skills ($n = 8$). No serious adverse events or safety concerns occurred among the study participants.

CONCLUSIONS: MM-based intervention is feasible, acceptable, and safe in opioid-treated CLBP

References:

1. Hilton, L., et al., *Mindfulness Meditation for Chronic Pain: Systematic Review and Meta-analysis*. Ann Behav Med, 2016.
2. Bawa, F.L., et al., *Does mindfulness improve outcomes in patients with chronic pain? Systematic review and meta-analysis*. Br J Gen Pract, 2015. **65**(635): p. e387-400.
3. Son Y, L.H., Chen H, Wang J., *Mindfulness intervention in the management of chronic pain and psychological comorbidity: a meta-analysis*. Int J Nurs Studies, 2014. **1**: p. 215-223.
4. Eilender, P., et al., *Treatment approaches for patients with opioid use disorder and chronic noncancer pain: A literature review*. Addictive Disorders and their Treatment, 2016. **15**(2): p. 85-98.
5. Zgierska, A.E., et al., *Mindfulness Meditation-Based Intervention Is Feasible, Acceptable, and Safe for Chronic Low Back Pain Requiring Long-Term Daily Opioid Therapy*. Journal of Alternative & Complementary Medicine, 2016. **22**(8): p. 610-20.
6. Gardiner, P., et al., *Integrative medical group visits: A pilot study to manage patients with comorbid chronic pain and depression*. Journal of Alternative and Complementary Medicine, 2016. **22** (6): p. A81.
7. Garland, E.L., et al., *Mindfulness-oriented recovery enhancement for chronic pain and prescription opioid misuse: results from an early-stage randomized controlled trial*. Journal of Consulting & Clinical Psychology, 2014. **82**(3): p. 448-59.
8. Fayaz, A., et al., *Prevalence of chronic pain in the UK: a systematic review and meta-analysis of population studies*. BMJ Open, 2016. **6**(6): p. e010364.
9. Breivik, H., et al., *The individual and societal burden of chronic pain in Europe: the case for strategic prioritisation and action to improve knowledge and availability of appropriate care*. BMC Public Health, 2013. **13**: p. 1229.
10. Vos, T., et al., *Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010*. Lancet, 2012. **380**(9859): p. 2163-96.
11. Foy, R., et al., *Prescribed opioids in primary care: cross-sectional and longitudinal analyses of influence of patient and practice characteristics*. BMJ Open, 2016. **6**(5): p. e010276.
12. Campbell, C.I., et al., *Age and gender trends in long-term opioid analgesic use for noncancer pain*. Am J Public Health, 2010. **100**(12): p. 2541-7.

PRIORITY BRIEFING ID 4

The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days. The briefing is in four parts:

- i. General context
- ii. The question in a research format
- iii. What the research evidence says
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QUESTION: Do volunteer visits enhance mental wellbeing for isolated inpatients and have an impact on the length of stay and recovery time in the community?

General context and definitions:

Volunteering in health and social care can include a wide range of activities, from befriending, signposting and administering patient surveys to providing specific services based on their professional background. Volunteering is defined for the purpose of this brief as unpaid activity conducted for the benefit of others beyond close relatives.

Isolated inpatients are defined as inpatients in the acute hospital setting who have little support or social contact with family or friends.

The question in a structured format: In considering this as a research question, we could frame it as:

<i>Population:</i>	Inpatients in the hospital setting with little or no support from family or friends
<i>Intervention:</i>	Scheduled visits from volunteers during hospital stay
<i>Comparator:</i>	Usual practice (open times for visits from family members/friends)
<i>Outcomes of Interest:</i>	Physical and mental well-being, quality of life Length of stay in hospital Long term recovery (post discharge)

What the research evidence says: *Scale of volunteering:* It is estimated that around three million people volunteer for health, disability and welfare organisations in England, the same number as the combined NHS and social care workforce¹. In a survey sent out to 166 acute trusts, in the 95 trusts that responded, the average number of volunteers per trust was 471¹. This number included volunteers recruited by the trust itself (360 on average) plus additional volunteers recruited and supported by external organisations (often from the voluntary sector) working within the hospital. The authors calculated that if this estimate was extrapolated to cover all acute trusts in England, this would add up to more than 78,000 volunteers. Volunteers in acute trusts may be recruited either directly by the trust or through an external (often voluntary sector) organisation that provides a specific service within the trust.

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Impact of volunteering: There is limited peer reviewed published evidence on the impact of volunteering to improve general well-being within the acute care system. Three systematic reviews have been published in recent years in discrete areas; on the impact of volunteers assisting with palliative care – both within the hospital setting and the home ², on the effectiveness of volunteers assisting with mealtimes in hospital settings ³ and on mobilising older acute medical in-patients (Baczynska 2016). All three systematic reviews comment on the relative dearth of published research despite the fact that volunteering is a common practice within and across these settings and contexts. All three reviews recommend the need for further robust evaluation.

There has been very little primary research on the impact of volunteers befriending or visiting patients to improve patient well-being and connectedness. Mramor et al. ⁵ reported on the Purposeful Visitation Program (PVP) which provided structured interactions for hospitalized geriatric patients using volunteers trained to elicit discussion about recreation and leisure. The goal of the program was to improve patients' orientation, level of calmness, and mood through guided cognitively stimulating interactions. Seven volunteers were trained and provided the program to 98 older adults on a geriatric inpatient hospital unit of a large academic medical centre. Ninety-nine percent of patients reported enjoying their volunteer visit, and 96% thought other patients would also benefit. Volunteers and staff observed improvements, primarily in patient mood, after visits, but the authors recognised that these were subjective impressions of change, and further structured evaluation is required. Hashash et al. ⁶ reported on the IBD Connect program – a peer volunteer visit programme for inpatients with inflammatory bowel disease. IBD Connect was shown to improve the communication of the disease with family and friends and was shown to reduce hospitalised patient stress. According to the authors, IBD Connect is now fully integrated into the medical team procedures. The authors concluded that “in an era of patient-centred outcomes and patient-centred care, it is becoming increasingly important to integrate peer volunteer services to improve the quality of in-patient care”.

There are many examples of volunteers helping in hospitals reported in the grey literature. The report by the Kings Fund on volunteering in acute trusts found that volunteers fulfil a variety of different roles, from befriending, peer support and hospitality activities to entertainment and collecting survey data ¹. The report also showed that increasingly volunteers are performing roles in many different areas like theatres, accident and emergency (A&E) and maternity units. In some hospitals, volunteers are being seen as an integral part of the care team rather than as an 'add-on', however the authors of the report noted there are tensions around the appropriateness of roles for volunteers and boundaries with staff roles ¹.

There are also examples in the grey literature of volunteers reducing isolation for people transitioning from hospital to home. Care Network Cambridgeshire (CNC) helps older, isolated and vulnerable people living in Cambridgeshire to stay independent, maintain social contact with friends and community and lead healthier and happier lives. Its Help at Home service supports isolated people discharged from hospital, providing volunteer support in the home that enables people to stay independent. In a service evaluation more than half of those responding said the service had helped them stay out of hospital, with local health professionals confirming this ⁷. Nesta (National Endowment for Science Technology and the Arts) worked with ten hospital trusts in England to support the creation of impact volunteering opportunities and look systematically at the impact of volunteers on patients, staff and trusts ⁸. The programme ran over 18 months. Their evaluation suggested that volunteering within hospitals shows promise as a way to maintain or improve patient experience and well-being outcomes and has the

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potential to relieve pressures on the healthcare system. The authors called for future research to provide sufficient resources for more rigorous evaluation of hospital volunteering to further understanding of what impact it can have for patients and other stakeholders, and to identify ways to further improve volunteering services.

Ongoing studies/ Trials in progress:

No ongoing trials were located. Befriending services by volunteers currently operate in the majority of hospitals across the region.

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: In 2013-14 there were 15.5 million hospital admissions, an increase of 2.5% from 2012-2103⁹. The greatest number of admissions by five-year age band (excluding newborn babies) was for patients aged 65 to 69 (1.3 million). There are no statistics available that can help estimate the number of inpatients who are/feel isolated. National statistics of persons living alone are perhaps relevant for this briefing. In 2016, 7.7 million people in UK households lived alone¹⁰. The largest change is in the 45 to 64 age group, where the number of people living alone increased by 23% between 2005 and 2015. Those aged 65 to 74, and those aged 75 and over, living alone, accounted for just under half of those living alone, totalling more than 3.5 million.

The potential for health improvement: The Kings Fund report on volunteering in health and care (2015) surmised that 'there are huge opportunities for volunteering to help transform health and social care services and bring about real improvements for patients and the wider public'. In their best case scenario, 'hospitals and other providers see the creation of volunteering opportunities as an essential part of their relationship with the communities they serve, as well as being a means of improving patient experience and promoting public health' (see below).

Scenarios for the future of volunteering in hospitals from the Kings Fund report:

Best Case: A strategic approach towards volunteering is taken, with providers considering the role of volunteers within their workforce planning processes. Hospitals systematically map the ways in which volunteers could add value in each department or service unit, pro-actively recruit people to fill the roles identified, and put appropriate support and training in place. Organisations make it their business to celebrate the contributions of volunteers, and find innovative ways of doing this. Volunteers are increasingly seen as being part of the care team and provide a trusted source of support to professionals.

Worst case: Volunteering continues to take place in hospitals and other settings but in a piecemeal way. NHS organisations fail to think strategically about the role of volunteers within their organisation and do not recruit volunteers pro-actively or provide adequate support. Quality assurance and oversight of volunteers' work is inadequate and leads to complaints from patients in some hospitals. Attempts to make volunteers a more integral part of the care team backfire as the unique strengths of volunteers such as flexibility and independence are lost in the process. As volunteer roles become more formalised, growing regulation places limits on volunteers' ability to be creative and personal with patients, adding to feelings of frustration.

The practicality of the research question: Volunteer befriending schemes are advertised as being available across the majority of hospitals in the South West region. Musgrave Park Hospital in Taunton and the RD&E in Exeter are actively recruiting for their Hospital Befriending programs (http://www.rdehospital.nhs.uk/patients/help/volunteer_vacancies.html-and

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<http://www.tsft.nhs.uk/patients-and-visitors/patient-experience/opportunities-for-musgrove-volunteers/>). The development of a 'befriending scheme' across Cornwall community hospitals is described in a recent blog (November 2016) – see <https://www.volunteercornwall.org.uk/blog/befriending>. Exploring the role of the volunteer beyond the hospital to help inpatients as they are discharged is an area which the Royal Voluntary Service has suggested is much needed ¹¹.

Whether the South West is a good place to do this research: In 2013 the Office for National Statistics reported that the South West was the region with the highest proportion of older people. The rate of net migration of older people from other regions into the South West was also the highest among the regions of England. Challenges such as the rurality of the region, where two thirds of the 37 local authorities (62%) are predominantly rural, may impact the level of social isolation experienced both in and out of hospital.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

Department of Health (2014) *The Adult Social Care Outcomes Framework 2015/16* : 'Improving patient experience of hospital care' is part of Domain Four within the framework - ensuring that people have a positive experience of care.

NICE Clinical Guideline 138 (2012): *Patient experience in adult NHS services: improving the experience of care for people using adult NHS services*.

Relevant Abstracts:

Mramor, B., Hagman, J., Ford, D., Oman, K. S. and Cumbler, E. (2015). Purposeful visits for hospitalized older adult patients. Journal of Gerontological Nursing. 41: 42-8

Hospitalization can be an isolating and stressful experience for older adults who find themselves cut off from normal routines and social support systems. The Purposeful Visitation Program (PVP) provided structured interactions for hospitalized geriatric patients using volunteers trained to elicit discussion about recreation and leisure. The goal of the program was to improve patients' orientation, level of calmness, and mood through guided cognitively stimulating interactions. Between January and July 2010, seven volunteers were trained and provided the program to 98 older adults on a geriatric inpatient hospital unit of a large academic medical center. Ninety-nine percent of patients reported enjoying their volunteer visit, and 96% thought other patients would also benefit. Volunteers and staff observed improvements, primarily in patient mood, after visits. PVP represents a cost-effective method of providing structured, individualized, and stimulating social interactions for older adults in a hospital setting. Copyright 2015, SLACK Incorporated.

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Babadu P, Trevithick P, Spath R. (2016) Measuring the impact of Helping in Hospitals: Final evaluation report. The Social Innovation Partnership/ NESTA. Available from: http://www.nesta.org.uk/sites/default/files/helping_in_hospitals_evaluation_report.pdf

CAN HOSPITAL IMPACT VOLUNTEERING HELP TO IMPROVE PATIENTS' EXPERIENCE AND WELL-BEING?
Portfolio-level results

Results from the nine hospital trusts' evaluations revealed the following:

1. Thirty per cent of all outcomes measured produced a statistically significant positive result
2. Of those hospital trusts that measured patient mood, nutrition and hydration levels and releasing time to care, the majority found statistically significant positive results while for the remaining hospital trusts no effects were found.
3. Of those hospital trusts that measured patient experience and anxiety levels, some of the hospital trusts found statistically significant positive results, while for others no effects were found.
4. Of those hospital trusts that measured readmissions, length of stay, delayed transfer of care and number of falls, no effects were found.
5. No hospital trusts found any statistically significant negative effects.

Germain, A., Doyle, R., Nolan, K., Gambles, M., Roberts, A., Smeding, R., Mason, S. and Ellershaw, J. E. (2015). PA3 Using the lived experience of volunteers to enhance the care of dying patients and their families. *BMJ supportive & palliative care*. 5 Suppl 1: A20

In the UK, the majority of people die in hospital.(1) Community presence is considered to be a significant component to achieving a "good death",(2,3) however many patients die with no/few visitors, spending their last weeks of life isolated or alone. To establish a Volunteer Service and offer: A presence to dying patients. A connection to the community outside the Hospital. Support to families, unable to visit or emotionally exhausted from their bedside vigil. The Service was piloted on 6 wards (October 2012-March 2013) within a large NHS Trust, in the North of England. This was followed by a comprehensive evaluation, according to MRC guidance. Analysis of the service evaluation indicated that the service was extremely beneficial, meeting its aims in providing an emotional support and spiritual presence to dying patients, and their families. The Service provides a model of best practice that could be replicated in other Trusts and within other care settings. There are plans to further develop and expand service provision across the Trust.

PRIORITY BRIEFING ID 4

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3. Edwards D, Carrier J, Hopkinson J. Mealtime assistance for older adults in hospital settings and rehabilitation units from the perspective of patients, families and healthcare professionals: a mixed methods systematic review. *JBI Database of Systematic Reviews And Implementation Reports.* 2016;14(9):261-357
4. Baczynska AM, Lim SE, Sayer AA, Roberts HC. The use of volunteers to help older medical patients mobilise in hospital: a systematic review. *J Clin Nurs.* 2016 Nov;25(21-22):3102-3111
5. Mramor B, Hagman J, Ford D, Oman KS and Cumbler E. (2015). Purposeful visits for hospitalized older adult patients. *J Gerontol Nurs.* 41: 42-8
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PRIORITY BRIEFING ID 18

The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days. The briefing is in four parts:

- i. General context
- ii. The question in a research format
- iii. What the research evidence says
- iv. Alignment with PenCLAHRC research priority criteria

QUESTION: How have practices changed since the Liverpool Care Pathway (for end of life care) was withdrawn and with what consequences?

General context and definitions: It is important to ensure that people die with dignity with their symptoms controlled as part of compassionate care – this is the premise of the Government’s renewed commitment to ending variation in end of life care (2016). The Liverpool Care Pathway (LCP) was developed to aid members of a multi-disciplinary team in matters relating to medical treatment and care during the last days and hours of a patient's life, aiming for consistency in care. It was a tool aimed to help health care teams consider the best they could achieve for a person in their last days of life (1). It was withdrawn in 2013 in favour of a more person-centred care approach where people approaching the end of life are ‘*offered comprehensive assessments in response to their changing needs and preferences, with the opportunity to discuss, develop and review a personalised care plan for current and future support and treatment*’ (NICE 2013)(2). Following an independent review, the LCP was withdrawn in light of concerns that it had been misused by staff with insufficient training in the context of inadequate clinical leadership, resulting in paradoxically poor care experiences.

The question in a structured format: In considering this as a research question, we could frame it as:

<i>Population:</i>	Adults needing end of life care in any health care setting including at home
<i>Intervention:</i>	End of life care services post LCP withdrawal
<i>Comparator:</i>	End of life care services pre LCP withdrawal
<i>Outcomes of Interest:</i>	Services provided – what, when, where, how Physical outcomes – hydration, pain, side effects, medications Wellbeing outcomes of patient (measured directly or via loved ones involved in care) – psychological distress, anxiety, comfort, Quality of care – staff, communication, decision making, recognition of end of life beginning.

What the research evidence says: There has been a recent (2016) systematic review (3) that has looked at the effects of end of life care pathways compared with no pathway. The review found only one cluster randomised trial to include, despite including any studies with a controlled study design.

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The one trial included was conducted in Italy and looked at the effectiveness of the LCP versus usual care in cancer patients in eight pairs of wards across 16 hospitals. This study was deemed by the review authors to have a high risk of bias. The study interviewed families after the death of their loved ones, looking at the overall quality of care, respect, dignity, kindness, advanced care planning and overall control of pain, breathlessness, nausea and vomiting. The study found that of the patients allocated to the LCP on average only 34% were cared for fully in accordance with the programme. Those on the LCP reportedly experienced better overall control of breathing than standard care (OR 2.0, 95% CI 1.1 to 3.8, P = 0.026) but for pain, nausea and vomiting the difference was not significant. There were no other outcomes reported.

More recently (2016) a national mixed methods study in the UK (4) (funded by the NIHR Health Services and Delivery Research (HSDR) programme) examined approaches to end of life care across two settings (nursing homes and intensive care units) and found many people were still using the LCP despite its withdrawal. The study aimed to collect data from nine sources: policy documents; retrospective analysis of 10 deaths in each location; interviews with staff; prospective observation of dying patients; case notes analysis; and interviews with staff and relatives. Observations were conducted in 12 sites, eight of which used the LCP. The study reported three subtle differences in the delivery of care between LCP using and non-LCP using ICUs and these were primarily related to the consistency in care. Care in units that did not use the LCP tended to be guided by the consultants' approach which varied by consultant and tended to mean the withdrawal of care was quicker or more immediate rather than gradual and considerate of the patient and their relatives. It also tended to mean the nurses spent less time at the bedside with the patient and their relatives as the lack of LCP seemed to give way to a more hands-off approach.

Further findings from this study suggest that the LCP was used and interpreted differently across sites. In nursing homes training in care of the dying was variable. Although at recruitment homes reported *not* using the LCP, by the time it came to data collection almost all were using some or significant parts of the LCP in their care. Other end of life care initiatives were also in use such as GSF, regional advanced care planning initiatives and the North West End of Life Care Six Steps to Success programme. Therefore attributing findings to the presence of LCP was very difficult. Nursing homes reported other challenges including appropriate timing for the multidisciplinary team assessment involving the GP, the need for some care procedures such as preventative care for pressure sores to be revisited during the last few hours/days of life. This was a concern for relatives. In ICU care, the role of the LCP pathway seemed unclear, with many reporting there was often not enough time to implement it. However, LCP was regarded positively, and was mainly seen as a tool to guide nursing care once a decision to withdraw treatment has been established by the consultant. The authors of this HSDR study (4) made several recommendations for research and practice in both care settings.

Ongoing studies/ Trials in progress:

Bettina Husebo, Elisabeth Flo, Knut Engedal. The Liverpool Care Pathway: discarded in cancer patients, but good enough for dying nursing home patients and people with dementia? A systematic review. PROSPERO 2016:CRD42016045802

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: In England and Wales over half a million people die each year. In those aged ≥ 65 years ($n=449,409$), the two most likely places of death are hospitals (52%) and nursing homes (22%), with 20% of deaths occurring at home, 5% in hospices and 1% elsewhere. In the South West (Cornwall, Devon and Somerset) there are approximately 21,163 deaths per year and with an increasingly ageing population being prepared for the end of life will also impact on the close family/friends/carers.

The potential for health improvement: Although deaths will not be prevented, the standard of care preceding hours/days of death can be improved with appropriate guidance and training. Despite the LCP being discontinued, it (or elements of it) are still in use in hospital and nursing homes. Practical implementation of the revised guidance (2015) may lead to more consistency in end of life care, leaving the families affected, having a more positive experience at the loss of their loved ones and avoiding unnecessary conflict and confusion during those last critical hours.

The practicality of the research question: All or most establishments dealing with end of life care are affected by the current guidance. Establishing what is currently being done, to what extent it follows the current guidance and what impact it is having on the end of life care experience can be measured in different ways.

Whether the South West is a good place to do this research: In 2013 the Office for National Statistics reported that the South West was the region with the highest proportion of older people. The rate of net migration of older people from other regions into the South West was also the highest among the regions of England. This indicates there is scope for a big difference to be made in the delivery and receipt of end of life care for patients, families, caring staff and other health professionals.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

There are current NICE guidelines as to what end of life care(5) should look like and a 2016 Health Service and Delivery Research report (4) suggests how the UK end of life care services are improving and where improvements still need to be made across the health and social care settings. Specifically it provides guidelines for:

- [recognising when people are entering the last few days of life](#)
- [communicating and shared decision-making](#)
- [clinically assisted hydration](#)
- [medicines for managing pain, breathlessness, nausea and vomiting, anxiety, delirium, agitation, and noisy respiratory secretions](#)
- [anticipatory prescribing](#)

Relevant Abstracts:

1. Chan Raymond J, Webster J, Bowers A. End-of-life care pathways for improving outcomes in caring for the dying. *Cochrane Database Syst Rev* [Internet]. 2016; (2).

Background: In many clinical areas, integrated care pathways are utilised as structured multidisciplinary care plans that detail essential steps in caring for patients with specific clinical problems. In particular, care pathways for the dying have been developed as a model to improve care of patients who are in the last days of life. The care pathways were designed with an aim of ensuring that the most appropriate management occurs at the most appropriate time, and that it is provided by the most appropriate health professional. Since the last update, there have been sustained concerns about the safety of implementing end-of-life care pathways, particularly in the United Kingdom (UK). Therefore, there is a significant need for clinicians and policy makers to be informed about the effects of end-of-life care pathways via a systematic review.

Objectives: To assess the effects of end-of-life care pathways, compared with usual care (no pathway) or with care guided by another end-of-life care pathway across all healthcare settings (e.g. hospitals, residential aged care facilities, community). In particular, we aimed to assess the effects on symptom severity and quality of life of people who are dying, or those related to the care, such as families, carers and health professionals, or a combination of these.

Search methods: We searched the Cochrane Central Register of Controlled Trials (CENTRAL; Cochrane Library; 2015, Issue 6), MEDLINE, EMBASE, PsycINFO, CINAHL, review articles, trial registries and reference lists of relevant articles. We conducted the original search in September 2009, and the second updated search in July 2015. Selection criteria All randomised controlled trials (RCTs), quasi-randomised trials or high quality controlled before-and-after studies comparing use versus non-use of an end-of-life care pathway in caring for the dying.

Main results: We screened 3028 titles, and included one Italian cluster RCT with 16 general medicine wards (inpatient units in hospitals) and 232 carers of cancer patients in this updated review. We judged the study to be at a high risk of bias overall, mainly due to a lack of blinding and rates of attrition. Only 34% of the participants (range 14% to 75% on individual wards) were cared for in accordance with the care pathway as planned. The study population was all cancer patients in their last days of life. Participants were allocated to care using the Liverpool Care Pathway (LCP-I, Italian version of a continuous quality improvement programme of end-of-life care) or to standard care. The primary outcomes of this review were physical symptom severity, psychological symptom severity, quality of life, and any adverse effects. Physical symptom severity was assessed as overall control of pain, breathlessness, and nausea and vomiting. There was very low quality evidence of a difference in overall control of breathlessness that favoured the Liverpool Care Pathway group compared to usual care: the study reported an odds ratio (OR) of 2.0 with 95% confidence intervals (CIs) 1.1 to 3.8. Very low quality evidence of no difference was found for pain (OR 1.3, 95% CI 0.7 to 2.6, $P = 0.461$) and nausea and vomiting (OR 1.5, 95% CI 0.7 to 3.2, $P = 0.252$). None of the other primary outcomes were assessed by the study. Limited data on advance care planning were collected by the study authors, making results for this secondary outcome unreliable. None of our other secondary outcomes were assessed by the study.

Authors' conclusions: There is limited available evidence concerning the clinical, physical, psychological or emotional effectiveness of end-of-life care pathways.

2. Perkins E, Gambles M, Houten R, Harper S, Haycox A, O'Brien T, et al. The care of dying people in nursing homes and intensive care units: a qualitative mixed-methods study. Southampton UK: Queen's Printer and Controller of HMSO 2016.

Background: In England and Wales the two most likely places of death are hospitals (52%) and nursing homes (22%). The Department of Health published its National End of Life Care Strategy in July 2008 (Department of Health. End of Life Care Strategy: Promoting High Quality Care For All Adults at the End of Life. London: Department of Health; 2008) to improve the provision of care, recommending the use of the Liverpool Care Pathway for the Dying Patient (LCP).

Aim: The original aim was to assess the impact of the LCP on care in two settings: nursing homes and intensive care units (ICUs). **Design:** Qualitative, matched case study.

Methods: Data were collected from 12 ICUs and 11 nursing homes in England: (1) documentary analysis of provider end-of-life care policy documents; (2) retrospective analysis of 10 deaths in each location using written case notes; (3) interviews with staff about end-of-life care; (4) observation of the care of dying patients; (5) analysis of the case notes pertaining to the observed patient's death; (6) interview with a member of staff providing care during the observed period; (7) interview with a bereaved relative present during the observation; (8) economic analysis focused on the observed patients; and (9) strict inclusion and selection criteria for nursing homes and ICUs applied to match sites on LCP use/non-LCP use.

Results: It was not possible to meet the stated aims of the study. Although 23 sites were recruited, observations were conducted in only 12 sites (eight using the LCP). A robust comparison on the basis of LCP use could not, therefore, take place. Although nurses in both settings reported that the LCP supported good care, the LCP was interpreted and used differently across sites, with the greatest variation in ICUs. Although not able to address the original research question, this study provides an unprecedented insight into care at the end of life in two different settings. The majority of nursing homes had implemented some kind of 'pathway' for dying patients and most homes participating in the observational stage were using the LCP. However, training in care of the dying was variable and specific issues were identified relating to general practitioner involvement, the use of anticipatory drugs and the assessment of consciousness and the swallowing reflex. In ICUs, end-of-life care was inextricably linked with the withdrawal of active treatment and controlling the pace of death. The data highlight how the decision to withdraw was made and, importantly, how relatives were involved in this process. The fact that most patients died soon after the withdrawal of interventions was reported to limit the appropriateness of the LCP in this setting.

Limitations: Although the recruitment of matched sites was achieved, variable site participation resulted in a skewed sample. Issues with the sample size and a blurring of LCP use and non-use limit the extent to which the ambitious aims of the study were achieved. **Conclusions:** This study makes a unique contribution to understanding the complexity of care at the end of life in two very different settings. More research is needed into the ways in which an organisational culture can be created within which the principles of good end-of-life care become translated into practice.

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References:

1. Julia Neuberger RB. The Liverpool Care Pathway: what went right and what went wrong. *Br J Hosp Med (Lond)*. 2016;77(3):172-4.
2. More Care, Less Pathway: An independent review of the Liverpool Care Pathway. 2013.
3. Chan Raymond J, Webster J, Bowers A. End-of-life care pathways for improving outcomes in caring for the dying. *Cochrane Database Syst Rev* [Internet]. 2016; (2). Available from: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008006.pub4/abstract>.
4. Perkins E, Gambles M, Houten R, Harper S, Haycox A, O'Brien T, et al. The care of dying people in nursing homes and intensive care units: a qualitative mixed-methods study. Southampton UK: Queen's Printer and Controller of HMSO 2016.
5. (NG31) NG. Care of dying adults in the last days of life. 2015.

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The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days. The briefing is in four parts:

- i. General context
- ii. The question in a research format
- iii. What the research evidence says
- iv. Alignment with PenCLAHRC research priority criteria

QUESTION: How can we best provide person centred continence care to adults with severe cognitive impairment in residential care settings?

General context and definitions: Continence is the ability to voluntarily control emptying the bladder and bowels effectively in a socially acceptable and hygienic way.

Severe cognitive impairment (or a dementia diagnosis) is associated with a higher prevalence of incontinence compared to people without such a diagnosis. People at the advanced stages of dementia may be unable to communicate their needs and may have multiple co-morbidities such as diabetes, hypertension and mobility problems all of which can contribute to incontinence.

Commonly used definitions of person centred care focus on putting people and their families at the centre of decisions and seeing them as experts, working alongside professionals to get the best outcome.

The question in a structured format: In considering this as a research question, we could frame it as:

<i>Population:</i>	Adults with severe cognitive impairment resident in care settings
<i>Intervention:</i>	Person centred approaches to continence care
<i>Comparator:</i>	Usual care
<i>Outcomes of</i>	Quality of life, agitation, infection rate, staff satisfaction, resources and costs
<i>Interest:</i>	

What the research evidence says: As might be expected, urinary incontinence is associated with reduced quality of life in care home residents. A large retrospective survey of over 133,000 older people resident in long term care facilities in the US found that new or worsening urinary incontinence decreased quality of life even in those who were frail and/or functionally and cognitively impaired¹. A further systematic review (of qualitative and quantitative research) of the perspectives of older people resident in care homes on having urinary incontinence found that residents who are able to voice their experiences do not expect their urinary incontinence to improve and believed it to be inevitable in old age. The authors concluded that little is known about how cognitively impaired residents perceive their condition².

A systematic review of systematic reviews of conservative behavioural approaches (toileting programmes, prompted voiding and the use of incontinence products) for the management of urinary

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incontinence and promotion of continence in older people in care homes published in 2014 found some evidence of effectiveness in the short term. There was, however, little evidence of the impact of associated factors e.g. exercise, mobility, comorbidities, hydration, skin care, staff perspectives and older people's experiences and preferences³.

Regular National Audits of Continence Care (NACC) carried out by the Royal College of Physicians and sponsored by the Healthcare Quality Improvement Partnership (HQIP), the latest in 2010⁴, show that despite the amount of guidance available the quality of continence care remains variable across the country, is poorer overall for the elderly and many continence assessments are conducted by providers without any basic training in continence. Despite efforts to encourage independent care home providers to participate all included care home data was provided by homes from either the Barchester Group (n=200) or the Anchor Trust (n=13). The authors of the audit comment that care homes found the process very difficult – some did not have the facilities to provide the required information and others found the content complicated.

Across all care settings, the audit found that healthcare professionals are not consistently:

- asking about incontinence in people who are at risk of the condition (e.g. older people),
- providing assessment, diagnosis and follow-through according to standard practice,
- communicating information about causes and treatments of patients' incontinence,
- asking patients about their own goals for treatment,
- assessing the impact of incontinence on quality of life or,
- making care plans to achieve treatment goals and sharing these with patients and (where relevant) carers.

Although the use of continence care plans was commonly reported in the care homes included in the audit (83%), for almost all (99%) residents, the use of integrated care pathways (34%) and treatment algorithms (6%) were less common and care plans were not commonly shared with residents (27%) and their families (54%). A full discussion of the causes and treatment of urinary incontinence with the family/carers was documented in 58% of residents.

Working with the results of these audits, national guidelines and research, NHS England produced a guidance document 'Excellence in Continence Care' in 2015 to help support best practice in continence care⁵. The importance of empowering people to be involved in the assessment, diagnosis and treatment of their incontinence is highlighted, indicating that full partnership in the delivery of person-centred care brings real choice through access to information, advice and treatment. The ability of the workforce to work in a person-centred way is central to this; the United Kingdom Continence Society (UKCS) minimum standards for continence care are provided as a basis for developing and supporting the workforce⁶.

A PenCLAHRC systematic review of approaches to implementation and dissemination in care homes [in preparation] identified 6 quantitative studies of changing practice in continence care in care homes published between 1992 and 2014 and 6 qualitative studies focussed on barriers and facilitators to change in this area published between 2002 and 2008. None of the studies was carried out in the UK.

Ongoing studies/ Trials in progress:

Goodman C, Rycroft Malone J, Norton C, Harari D, Harwood R, Roe B, Russell B, Fader M, Buswell M, Drennan VM, Bunn F. Reducing and managing faecal incontinence in people with advanced dementia who are resident in care homes: protocol for a realist synthesis. *BMJ Open* 2015; 5:e007728. doi: 10.1136/bmjopen-2015-007728

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: There are over 14 million adults with bladder control problems and six and a half million with bowel control problems in the UK⁷. Currently, 850,000 people in the United Kingdom are living with dementia, and this figure is estimated to rise to over two million by 2051⁸. A large proportion of the estimated 400,000 residents in UK care homes have dementia or another form of cognitive impairment⁹. Urinary incontinence is a prevalent condition in care home populations.

The potential for health improvement: Urinary incontinence is a prevalent condition in care home populations; those with severe cognitive impairment are likely to have complex continence assessment and management needs. The National Audit on Continence Care provides evidence that despite the amount of guidance available the quality of continence care remains variable across the country and is poorer overall for the elderly indicating the potential for health improvement in this area. Improvements in basic training in continence may be important.

The practicality of the research question: Given the findings from the National Audit of Continence Care⁴ and the subsequent guidance document from NHS England this question may be more suited to the evaluation of the implementation of person centred practice in continence care than the effectiveness of interventions. Improving the understanding of provision of continence care across the many independently owned care homes in the South West would be important.

More detailed exploration of the evidence from qualitative and quantitative research on the implementation and dissemination of best practice in continence care would be relatively straightforward as an additional output from the larger PenCLAHRC review of evidence in implementation and dissemination in care homes.

Whether the South West is a good place to do this research: This question arose from a meeting with care home staff who had concerns over the rationing of continence products and the impact of this on their ability to provide person centred care to their residents. This issue was perceived to be particularly difficult in residents with severe cognitive impairment.

The National Audit of Continence Care⁴ found evidence for widespread rationing across health settings; 55% of care homes reported a limit on the provision of continence pads (4 per day) most commonly imposed by local community service, with additional products most commonly provided by the home.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

NHS England Excellence in Continence Care (2015) Practical guidance for commissioners, providers, health and social care staff and information for the public
<https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/11/EICC-guidance-final-document.pdf>

Royal College of Nursing (2007) Continence care in care homes: a framework to gather and share key information. https://www2.rcn.org.uk/_data/assets/pdf_file/0003/78555/001952.pdf

NICE Clinical guideline 49 Faecal incontinence: The management of faecal incontinence in adults (2007) (reviewed 2014) <http://www.nice.org.uk/guidance/cg49>

NICE Clinical guideline 171 Urinary incontinence in women: Management (2015) <https://www.nice.org.uk/guidance/cg171>

European Association of Urology Guidelines on Urinary Incontinence (2015) http://uroweb.org/wp-content/uploads/20-Urinary-Incontinence_LR1.pdf

UKCS Minimum standards for continence care in the United Kingdom (2015) <http://www.ukcs.uk.net/>

All Party Parliamentary Group (2011) Cost-effect Commissioning for Continence Care
<http://www.appgcontinence.org.uk/pdfs/CommissioningGuideWEB.pdf>

Healthcare Quality Improvement Partnership (HQIP) & Royal College of Physicians (2010) National Audit of Continence Care: Combined Organisational and Clinical Report
<https://www.rcplondon.ac.uk/sites/default/files/full-organisational-and-clinical-reportnacc-2010.pdf>

Relevant Abstracts:

Dubeau CE, Simon SE, Morris JN. The effect of urinary incontinence on quality of life in older nursing home residents. J Am Geriatr Soc. 2006 Sep; 54(9): 1325-33.

OBJECTIVES: To determine whether nursing home residents with urinary incontinence (UI) have worse quality of life (QoL) than continent residents, whether the relationship between UI and QoL differs across strata of cognitive and functional impairment, and whether change in continence status is associated with change in QoL.

DESIGN: Retrospective cohort study using a Minimum Data Set (MDS) database to determine cross-sectional and longitudinal (6 month) associations between UI and QoL.

SETTING: All Medicare- or Medicaid-licensed nursing homes in Kansas, Maine, Mississippi, New York, and South Dakota during 1994 to 1996.

PARTICIPANTS: All residents aged 65 and older, excluding persons unable to void or with potentially unstable continence or QoL status (recent nursing home admission, coexistent delirium, large change in functional status, comatose, near death).

MEASUREMENTS: UI was defined as consistent leakage at least twice weekly over 3 months and continence as consistent dryness over 3 months. QoL was measured using the validated MDS-derived Social Engagement Scale.

RESULTS: Of 133,111 eligible residents, 90,538 had consistent continence status, 58,850 (65%) of whom were incontinent. UI was significantly associated with worse QoL in residents with moderate cognitive and functional impairment. New or worsening UI over 6 months was associated with worse QoL (odds

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ratio = 1.46, 95% confidence interval = 1.36-1.57) and was second only to cognitive decline and functional decline in predicting worse QoL.

CONCLUSION: This is the first study to quantitatively demonstrate that prevalent and new or worsening UI decreases QoL even in frail, functionally and cognitively impaired nursing home residents. These results provide a crucial incentive to improve continence care and quality in nursing homes and a rationale for targeting interventions to those residents most likely to benefit.

Ostaszkiwicz J, O'Connell B, Dunning T. Residents' perspectives on urinary incontinence: a review of literature. Scand J Caring Sci. 2012 Dec; 26(4): 761-72.

BACKGROUND: Individuals in residential aged care facilities experience urinary incontinence more than any other single population. Despite these factors, the impact of the condition on their quality of life, their perspectives of living with the condition, and their preferences for care have received little research attention.

AIM: To provide a descriptive overview of research about; the impact of urinary incontinence on residents' quality of life; residents' perspectives of having urinary incontinence; and their preferences for continence care'.

DESIGN: A descriptive review of literature.

METHOD: A broad search was undertaken for qualitative and quantitative research that evaluated residents' quality of life related to urinary incontinence; their perspectives on having urinary incontinence, and their preferences for managing it. Data were displayed in tabular format, summarized, and described.

RESULTS: Ten studies were identified and reviewed (six qualitative and four quantitative). They reveal many residents' value having independent bowel and bladder function, but believe that incontinence is inevitable and intractable. Some adopt self-management strategies, however considerable barriers hinder their ability to maintain continence and manage incontinence. Residents often have low expectations, and hence decline further evaluation and treatment. Some express satisfaction with continence care even if this care is not consistent with their preferences. Little is known about how cognitively impaired residents perceive their condition. However some individuals with cognitive impairment respond with acute anxiety when carers' attempt to provide continence care.

CONCLUSION: Residents' perspectives on incontinence and preferences for continence care relate to low expectations for improvement. Such misconceptions should be addressed and residents and their family members should be given a range of options from which to choose. As urinary incontinence impacts on residents' quality of life, it is also important that continence care is delivered in a participative and sensitive way.

Roe B, Flanagan L, Maden M. Systematic review of systematic reviews for the management of urinary incontinence and promotion of continence using conservative behavioural approaches in older people in care homes. J Adv Nurs. 2015 Jul; 71(7): 1464-83

AIM: To synthesize evidence from systematic reviews on the management of urinary incontinence and promotion of continence using conservative/behavioural approaches in older people in care homes to inform clinical practice, guidelines and research.

BACKGROUND: Incontinence is highly prevalent in older people in care home populations.

DESIGN: Systematic review of systematic reviews with narrative synthesis.

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DATA SOURCES: Electronic searches of published systematic reviews in English using MEDLINE and CINAHL with no date restrictions up to September 2013. Searches supplemented by hand searching and electronic searching of Cochrane Library and PROSPERO.

REVIEW METHODS: PRISMA statement was followed, as were established methods for systematic review of systematic reviews.

RESULTS: Five systematic reviews of high quality were included, three specific to intervention studies and two reviewed descriptive studies. Urinary incontinence was the primary outcome in three reviews with factors associated with the management of urinary incontinence the primary outcome for the other reviews.

CONCLUSION: Toileting programmes, in particular prompted voiding, with use of incontinence pads are the main conservative behavioural approach for the management of incontinence and promotion of continence in this population with evidence of effectiveness in the short term. Evidence from associated factors; exercise, mobility, comorbidities, hydration, skin care, staff perspectives, policies and older people's experiences and preference are limited. The majority of evidence of effectiveness are from studies from one country which may or may not be transferable to other care home populations. Future international studies are warranted of complex combined interventions using mixed methods to provide evidence of effectiveness, context of implementation and economic evaluation.

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The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days. The briefing is in four parts:

- i. General context
- ii. The question in a research format
- iii. What the research evidence says
- iv. Alignment with PenCLAHRC research priority criteria

QUESTION: How can routinely collected data from primary care be used more effectively to identify both summative and unique side effects of polypharmacy?

General context and definitions: *Routinely collected data from primary care:* The most commonly cited example of this type of data resource in the research literature is the Clinical Practice Research Datalink (CPRD) which is a governmental, not-for-profit research service, jointly funded by the NHS national Institute for Health Research (NIHR) and the Medicines and Healthcare products Regulatory Agency (MHRA). As of October 2016, 711 GP practices were registered with the main CPRD database and providing data to support the ongoing clinical care and management of 14.64 million patients. The data available to researchers includes demographics, symptoms and signs, tests, clinical events (including diagnoses), immunisations, prescriptions and interventions, lifestyle information (e.g. smoking and alcohol status) and referrals to secondary care. CPRD can also provide linkage with datasets from secondary care, disease-specific cohorts and mortality records to enhance research potential. (*other examples of routine data are provided after the structured question below)

Polypharmacy: Polypharmacy is the concurrent use of multiple medications by one person. Although, generally considered as undesirable, there are many situations in which polypharmacy is therapeutically beneficial. In the King’s Fund report on polypharmacy and medicine’s optimisation published in 2013¹, *appropriate polypharmacy* was defined as ‘prescribing for an individual for complex conditions or for multiple conditions in circumstances where medicines use has been optimised and where the medicines are prescribed according to best evidence’ and *problematic polypharmacy* was defined as ‘the prescribing of multiple medications inappropriately, or where the intended benefit of the medication is not realised’. These definitions were incorporated in the NICE Guideline on Medicines Optimisation published in 2015². Polypharmacy may be harmful in that it can increase the risk of drug interactions and adverse drug reactions, together with impairing medication adherence and quality of life for patients.

The question in a structured format: In considering this as a research question, we could frame it as:

<i>Population:</i>	Routinely collected data from primary care
<i>Intervention:</i>	Statistical interrogation / analysis
<i>Comparator:</i>	N/A
<i>Outcomes of Interest:</i>	Summative and unique side effects of polypharmacy

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*Other examples of routine data include The Health Improvement Network (THIN) database, QResearch® and ResearchOne. The Health Improvement Network (THIN) database (<https://www.ucl.ac.uk/pcph/research-groups-themes/thin-pub/database>), is managed by researchers at UCL and currently contains the electronic medical records of 11.1 million patients (3.7 million active patients) collected from 562 general practices using Vision software. QResearch® (<http://www.qresearch.org>) contains data from approximately 1300 general practices using the EMIS clinical computer system and is managed by researchers at the University of Nottingham. ResearchOne (<http://www.researchone.org/>) is a much newer resource which draws from electronic health records in primary and secondary care providers including general practice, community care, child health, palliative hospital, acute hospital, urgent care, accident and emergency and out-of-hours services. ResearchOne is a collaboration between the software developers TPP, researchers at the University of Leeds and the UK Government's Technology Strategy Board.

What the research evidence says: We were unable to identify any research publications that have specifically used anonymised routinely collected data from primary care to investigate side effects of polypharmacy.

Three primary research studies were identified in which researchers used CRPD to investigate the prevalence of various aspects of polypharmacy. Ble and colleagues investigate the prevalence, trends over time, correlates and appropriateness of both any and long-term prescription of drugs with a higher risk-to benefit ratio (according to the 2012 Beers Criteria)³. Stocks and colleagues examined variations in the prevalence of different types of potentially hazardous prescribing in general practice⁴ and Bradley and colleagues used the CRPD data to estimate the prevalence of and factors associated with potentially inappropriate prescriptions in those aged over 70 years⁵. The authors of these studies comment on the accuracy of the prescription data in CRPD. Some of the challenges discussed include the ambiguity of Read codes for clinical diagnoses⁵ and missing medications prescribed on hand-written scripts which may be more prevalent during home visits³. QResearch® and the THIN database have also been used to investigate prevalence of polypharmacy^{6,7} whilst ResearchOne has been used to develop an electronic frailty index using similar methods⁸.

A paper published in 2016 describing a novel model and automated text-mining method to extract detailed structured medication information (dose number, dose frequency, dose interval and dose unit) from free-text prescriptions found a substantial proportion of records in CRPD had flexibility or variability in prescribed dosage and/or frequency. The evaluation process revealed reliable performance of the model with an overall accuracy of over 90 %, suggesting that it could be useful for exploring prescription patterns on a large scale⁹.

There are also a number of studies in the literature that show the utility of using primary health care data and electronic health record to identify medicine-related adverse events not captured by adverse reaction reporting systems^{10,11}.

Ongoing studies/ Trials in progress:

No ongoing trials found.

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: Data from the Health and Social Care Information Centre (HSCIC) shows that between 2003 and 2013 the average number of prescription items per year for any one person in England increased from 13 (in 2003) to 19 (in 2013). As the population ages and life expectancy increases, more people are living with several long-term conditions that are being managed with an increasing number of medicines. Maintaining a careful balance gets more difficult for people and health professionals, particularly when also trying to reduce health inequalities of the population. The risk of people suffering harm from their medicines as a result of side effects or interactions with other medicines increases with polypharmacy.

The potential for health improvement: Using routinely collected data to improve our understanding of the adverse effects associated with commonly co-prescribed medications could have important implications for an ageing population. The question was inspired by this TEDMED talk https://www.ted.com/talks/russ_altman_what_really_happens_when_you_mix_medications?language=en

The practicality of the research question: The question submitter suggested the following approach to interrogating the big data sources. Identification of combinations of two (then multiple) drugs that are associated with an increased reporting of common symptom phrases, new diagnosis formulations or biochemical changes. Comparison of these rates with the baseline rates for each drug individually, giving an odds ratio of incidence of enhanced or new side-effects when taking multiple drugs.

Whether the South West is a good place to do this research: There are several research groups with an active interest in polypharmacy at the University of Exeter as well as researchers with skills and experience of using the CRPD database³. Researchers from PenCLAHRC are also working with the team that used data from the CRPD database to develop an electronic frailty index⁸.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

N/A

Relevant Abstracts:

Ble A, Masoli JA, Barry HE, Winder RE, Tavakoly B, Henley WE, Kuchel GA, Valderas JM, Melzer D, Richards SH. Any versus long-term prescribing of high risk medications in older people using 2012 Beers Criteria: results from three cross-sectional samples of primary care records for 2003/4, 2007/8 and 2011/12. BMC Geriatr. 2015 Nov 5;15:146.

BACKGROUND: High risk medications are commonly prescribed to older US patients. Currently, less is known about high risk medication prescribing in other Western Countries, including the UK. We measured trends and correlates of high risk medication prescribing in a subset of the older UK population (community/institutionalized) to inform harm minimization efforts.

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METHODS: Three cross-sectional samples from primary care electronic clinical records (UK Clinical Practice Research Datalink, CPRD) in fiscal years 2003/04, 2007/08 and 2011/12 were taken. This yielded a sample of 13,900 people aged 65 years or over from 504 UK general practices. High risk medications were defined by 2012 Beers Criteria adapted for the UK. Using descriptive statistical methods and regression modelling, prevalence of 'any' (drugs prescribed at least once per year) and 'long-term' (drugs prescribed all quarters of year) high risk medication prescribing and correlates were determined.

RESULTS: While polypharmacy rates have risen sharply, high risk medication prevalence has remained stable across a decade. A third of older (65+) people are exposed to high risk medications, but only half of the total prevalence was long-term (any = 38.4 % [95 % CI: 36.3, 40.5]; long-term = 17.4 % [15.9, 19.9] in 2011/12). Long-term but not any high risk medication exposure was associated with older ages (85 years or over). Women and people with higher polypharmacy burden were at greater risk of exposure; lower socio-economic status was not associated. Ten drugs/drug classes accounted for most of high risk medication prescribing in 2011/12.

CONCLUSIONS: High risk medication prescribing has not increased over time against a background of increasing polypharmacy in the UK. Half of patients receiving high risk medications do so for less than a year. Reducing or optimising the use of a limited number of drugs could dramatically reduce high risk medications in older people. Further research is needed to investigate why the oldest old and women are at greater risk. Interventions to reduce high risk medications may need to target shorter and long-term use separately.

Stocks SJ, Kontopantelis E, Akbarov A, Rodgers S, Avery AJ, Ashcroft DM. Examining variations in prescribing safety in UK general practice: cross sectional study using the Clinical Practice Research Datalink. BMJ. 2015 Nov 3;351:h5501.

STUDY QUESTION: What is the prevalence of different types of potentially hazardous prescribing in general practice in the United Kingdom, and what is the variation between practices?

METHODS: A cross sectional study included all adult patients potentially at risk of a prescribing or monitoring error defined by a combination of diagnoses and prescriptions in 526 general practices contributing to the Clinical Practice Research Datalink (CPRD) up to 1 April 2013. Primary outcomes were the prevalence of potentially hazardous prescriptions of anticoagulants, anti-platelets, NSAIDs, β blockers, glitazones, metformin, digoxin, antipsychotics, combined hormonal contraceptives, and oestrogens and monitoring by blood test less frequently than recommended for patients with repeated prescriptions of angiotensin converting enzyme inhibitors and loop diuretics, amiodarone, methotrexate, lithium, or warfarin.

STUDY ANSWER AND LIMITATIONS: 49 927 of 949 552 patients at risk triggered at least one prescribing indicator (5.26%, 95% confidence interval 5.21% to 5.30%) and 21 501 of 182 721 (11.8%, 11.6% to 11.9%) triggered at least one monitoring indicator. The prevalence of different types of potentially hazardous prescribing ranged from almost zero to 10.2%, and for inadequate monitoring ranged from 10.4% to 41.9%. Older patients and those prescribed multiple repeat medications had significantly higher risks of triggering a prescribing indicator whereas younger patients with fewer repeat prescriptions had significantly higher risk of triggering a monitoring indicator. There was high variation between practices for some indicators. Though prescribing safety indicators describe prescribing patterns that can increase the risk of harm to the patient and should generally be avoided, there will always be exceptions where the indicator is clinically justified. Furthermore there is the possibility that

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some information is not captured by CPRD for some practices—for example, INR results in patients receiving warfarin.

WHAT THIS STUDY ADDS: The high prevalence for certain indicators emphasises existing prescribing risks and the need for their appropriate consideration within primary care, particularly for older patients and those taking multiple medications. The high variation between practices indicates potential for improvement through targeted practice level intervention.

Bradley MC, Motterlini N, Padmanabhan S, Cahir C, Williams T, Fahey T, Hughes CM. Potentially inappropriate prescribing among older people in the United Kingdom. BMC Geriatr. 2014 Jun 12;14:72.

BACKGROUND: Potentially inappropriate prescribing (PIP) in older people is associated with increases in morbidity, hospitalisation and mortality. The objective of this study was to estimate the prevalence of and factors associated with PIP, among those aged ≥ 70 years, in the United Kingdom, using a comprehensive set of prescribing indicators and comparing these to estimates obtained from a truncated set of the same indicators.

METHODS: A retrospective cross-sectional study was carried out in the UK Clinical Practice Research Datalink (CPRD), in 2007. Participants included those aged ≥ 70 years, in CPRD. Fifty-two PIP indicators from the Screening Tool of Older Persons Potentially Inappropriate Prescriptions (STOPP) criteria were applied to data on prescribed drugs and clinical diagnoses. Overall prevalence of PIP and prevalence according to individual STOPP criteria were estimated. The relationship between PIP and polypharmacy (≥ 4 medications), comorbidity, age, and gender was examined. A truncated, subset of 28 STOPP criteria that were used in two previous studies, were further applied to the data to facilitate comparison.

RESULTS: Using 52 indicators, the overall prevalence of PIP in the study population ($n = 1,019,491$) was 29%. The most common examples of PIP were therapeutic duplication (11.9%), followed by use of aspirin with no indication (11.3%) and inappropriate use of proton pump inhibitors (PPIs) (3.7%). PIP was strongly associated with polypharmacy (Odds Ratio 18.2, 95% Confidence Intervals, 18.0-18.4, $P < 0.05$). PIP was more common in those aged 70-74 years vs. 85 years or more and in males. Application of the smaller subset of the STOPP criteria resulted in a lower PIP prevalence at 14.9% (95% CIs 14.8-14.9%) ($n = 151,598$). The most common PIP issues identified with this subset were use of PPIs at maximum dose for > 8 weeks, NSAIDs for > 3 months, and use of long-term neuroleptics.

CONCLUSIONS: PIP was prevalent in the UK and increased with polypharmacy. Application of the comprehensive set of STOPP criteria allowed more accurate estimation of PIP compared to the subset of criteria used in previous studies. These findings may provide a focus for targeted interventions to reduce PIP.

Zhou X, Murugesan S, Bhullar H, Liu Q, Cai B, Wentworth C, Bate A. An evaluation of the THIN database in the OMOP Common Data Model for active drug safety surveillance. Drug Saf. 2013 Feb;36(2):119-34.

BACKGROUND: There has been increased interest in using multiple observational databases to understand the safety profile of medical products during the postmarketing period. However, it is challenging to perform analyses across these heterogeneous data sources. The Observational Medical Outcome Partnership (OMOP) provides a Common Data Model (CDM) for organizing and standardizing databases. OMOP's work with the CDM has primarily focused on US databases. As a participant in the

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OMOP Extended Consortium, we implemented the OMOP CDM on the UK Electronic Healthcare Record database-The Health Improvement Network (THIN).

OBJECTIVE: The aim of the study was to evaluate the implementation of the THIN database in the OMOP CDM and explore its use for active drug safety surveillance.

METHODS: Following the OMOP CDM specification, the raw THIN database was mapped into a CDM THIN database. Ten Drugs of Interest (DOI) and nine Health Outcomes of Interest (HOI), defined and focused by the OMOP, were created using the CDM THIN database. Quantitative comparison of raw THIN to CDM THIN was performed by execution and analysis of OMOP standardized reports and additional analyses. The practical value of CDM THIN for drug safety and pharmaco-epidemiological research was assessed by implementing three analysis methods: Proportional Reporting Ratio (PRR), Univariate Self-Case Control Series (USCCS) and High-Dimensional Propensity Score (HDPS). A published study using raw THIN data was selected to examine the external validity of CDM THIN.

RESULTS: Overall demographic characteristics were the same in both databases. Mapping medical and drug codes into the OMOP terminology dictionary was incomplete: 25 % medical codes and 55 % drug codes in raw THIN were not listed in the OMOP terminology dictionary, representing 6 % condition occurrence counts, 4 % procedure occurrence counts and 7 % drug exposure counts in raw THIN. Seven DOIs had <0.3 % and three DOIs had 1 % of unmapped drug exposure counts; each HOI had at least one definition with no or minimal (≤ 0.2 %) issues with unmapped condition occurrence counts, except for the upper gastrointestinal (UGI) ulcer hospitalization cohort. The application of PRR, USCCS and HDPS found, respectively, a sensitivity of 67, 78 and 50 %, and a specificity of 68, 59 and 76 %, suggesting that safety issues defined as known by the OMOP could be identified in CDM THIN, with imperfect performance. Similar PRR scores were produced using both CDM THIN and raw THIN, while the execution time was twice as fast on CDM THIN. There was close replication of demographic distribution, death rate and prescription pattern and trend in the published study population and the cohort of CDM THIN.

CONCLUSIONS: This research demonstrated that information loss due to incomplete mapping of medical and drug codes as well as data structure in the current CDM THIN limits its use for all possible epidemiological evaluation studies. Current HOIs and DOIs predefined by the OMOP were constructed with minimal loss of information and can be used for active surveillance methodological research. The OMOP CDM THIN can be a valuable tool for multiple aspects of pharmaco-epidemiological research when the unique features of UK Electronic Health Records are incorporated in the OMOP library.

Clegg A, Bates C, Young J, Ryan R, Nichols L, Ann Teale E, Mohammed MA, Parry J, Marshall T. Development and validation of an electronic frailty index using routine primary care electronic health record data. Age Ageing. 2016 May;45(3):353-60.

BACKGROUND: frailty is an especially problematic expression of population ageing. International guidelines recommend routine identification of frailty to provide evidence-based treatment, but currently available tools require additional resource.

OBJECTIVES: to develop and validate an electronic frailty index (eFI) using routinely available primary care electronic health record data.

STUDY DESIGN AND SETTING: retrospective cohort study. Development and internal validation cohorts were established using a randomly split sample of the ResearchOne primary care database. External validation cohort established using THIN database.

PARTICIPANTS: patients aged 65-95, registered with a ResearchOne or THIN practice on 14 October 2008.

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PREDICTORS: we constructed the eFI using the cumulative deficit frailty model as our theoretical framework. The eFI score is calculated by the presence or absence of individual deficits as a proportion of the total possible. Categories of fit, mild, moderate and severe frailty were defined using population quartiles.

OUTCOMES: outcomes were 1-, 3- and 5-year mortality, hospitalisation and nursing home admission.

STATISTICAL ANALYSIS: hazard ratios (HRs) were estimated using bivariate and multivariate Cox regression analyses. Discrimination was assessed using receiver operating characteristic (ROC) curves. Calibration was assessed using pseudo-R(2) estimates.

RESULTS: we include data from a total of 931,541 patients. The eFI incorporates 36 deficits constructed using 2,171 CTV3 codes. One-year adjusted HR for mortality was 1.92 (95% CI 1.81-2.04) for mild frailty, 3.10 (95% CI 2.91-3.31) for moderate frailty and 4.52 (95% CI 4.16-4.91) for severe frailty. Corresponding estimates for hospitalisation were 1.93 (95% CI 1.86-2.01), 3.04 (95% CI 2.90-3.19) and 4.73 (95% CI 4.43-5.06) and for nursing home admission were 1.89 (95% CI 1.63-2.15), 3.19 (95% CI 2.73-3.73) and 4.76 (95% CI 3.92-5.77), with good to moderate discrimination but low calibration estimates.

CONCLUSIONS: the eFI uses routine data to identify older people with mild, moderate and severe frailty, with robust predictive validity for outcomes of mortality, hospitalisation and nursing home admission. Routine implementation of the eFI could enable delivery of evidence-based interventions to improve outcomes for this vulnerable group.

Tatonetti NP1, Ye PP, Daneshjou R, Altman RB. Data-driven prediction of drug effects and interactions. *Sci Transl Med.* 2012 Mar 14;4(125):125ra31.

Adverse drug events remain a leading cause of morbidity and mortality around the world. Many adverse events are not detected during clinical trials before a drug receives approval for use in the clinic. Fortunately, as part of postmarketing surveillance, regulatory agencies and other institutions maintain large collections of adverse event reports, and these databases present an opportunity to study drug effects from patient population data. However, confounding factors such as concomitant medications, patient demographics, patient medical histories, and reasons for prescribing a drug often are uncharacterized in spontaneous reporting systems, and these omissions can limit the use of quantitative signal detection methods used in the analysis of such data. Here, we present an adaptive data-driven approach for correcting these factors in cases for which the covariates are unknown or unmeasured and combine this approach with existing methods to improve analyses of drug effects using three test data sets. We also present a comprehensive database of drug effects (Offsides) and a database of drug-drug interaction side effects (Twosides). To demonstrate the biological use of these new resources, we used them to identify drug targets, predict drug indications, and discover drug class interactions. We then corroborated 47 ($P < 0.0001$) of the drug class interactions using an independent analysis of electronic medical records. Our analysis suggests that combined treatment with selective serotonin reuptake inhibitors and thiazides is associated with significantly increased incidence of prolonged QT intervals. We conclude that confounding effects from covariates in observational clinical data can be controlled in data analyses and thus improve the detection and prediction of adverse drug effects and interactions

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The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days. The briefing is in four parts:

- i. General context
- ii. The question in a research format
- iii. What the research evidence says
- iv. Alignment with PenCLAHRC research priority criteria

QUESTION: Is nature based Cognitive Stimulation Therapy (CST) as effective as existing CST for people with dementia? Are there people for whom nature based CST is preferable? Does nature enhance people’s experience of CST sessions?

General context and definitions: ‘*Cognitive Stimulation Therapy*’ is an intervention for people with dementia which offers a range of enjoyable activities providing general stimulation for thinking, concentration and memory usually in a social setting, such as a small group.

Dementia is one of the major causes of disability and dependency among older people worldwide. It is a syndrome in which there is a deterioration in cognitive function affecting memory, behaviour and ability to perform everyday activities. CST is one of a number of approaches to help people with dementia improve their cognitive skills and comprises 14 sessions of structured 45 minute group therapy sessions. The sessions run over 7 weeks and cover a range of activities to stimulate thinking and memory such as discussing past and present events, listening to music, playing word games and doing practical activities such as baking or indoor gardening. The sessions are designed to be enjoyable and an opportunity to be with others in a social setting. The National Institute for Health and Care Excellence (NICE) and Social Care Institute for Excellence (SCIE) guidance¹ recommends that people with mild to moderate dementia should be given the opportunity to take part in a CST programme.

CST can be conducted in various settings such as residential homes, day care centres and memory clinics. It can also be delivered in the natural environment: an example is the Sydenham Garden *Sow and Grow* project² which uses CST to support people with early stages of dementia to live well. That people living with dementia can potentially benefit from CST delivered in a natural setting is supported by a number of studies showing how ‘green care’ which includes care farming, gardens and therapeutic horticulture, benefits those living with dementia.³⁻⁵

The question in a structured format: In considering this as a research question, we could frame it as following:

Population:	People living with mild to moderate dementia
Intervention:	Nature based CST programme
Comparator:	Non-nature CST
Outcomes:	Cognitive function, Quality of Life, Wellbeing, Social and communication, Depression, Carer wellbeing

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What the research evidence says: There is clear evidence on the benefit of CST. One Cochrane review⁶ and a number of systematic reviews have shown that CST benefits cognition in people with mild to moderate dementia over and above any mediation effects.⁷⁻⁹ These reviews also reported improvements in quality of life for people with dementia.

A qualitative study investigated whether improvements found in clinical trials were also noted by people with dementia, their carers and group facilitators in everyday life.¹⁰ Data gathered from qualitative interviews and focus groups were analysed and two main themes emerged which were 'positive experience of being in the group' and 'changes experienced in everyday life'. Under the theme 'positive experience of being in the group', four subthemes were identified: (i) positive feelings were experienced during the CST group as it made them feel more positive, relaxed, and confident and that they wanted to continue with the group; (ii) listening to others and feeling able to talk contrasted the feelings of loneliness and a passive state of mind that emerges when they were alone at home; (iii) sharing a diagnosis made them realise that they were not alone and this made them feel supported; (iv) the supportive and nonthreatening environment in the CST group created an opportunity to gain support and also to provide support to others. Three subthemes were identified under the theme 'changes experienced in everyday life: (i) finding talking easier in a group environment during CST and some showed greater willingness to engage in conversation; (ii) improvement in memory; and (iii) improvement in concentration and alertness.

Although no systematic reviews or published primary research studies on nature-based CST for people with dementia were found, there is an emerging body of evidence on how the natural environment benefits older people living with dementia. In its 2013 report, *Greening Dementia*,¹¹ Natural England explored the benefits of outdoor engagement for people with dementia, concluding that access to the natural environment facilitated improved emotional and physical health; increased verbal expression, memory and awareness; a greater sense of general well-being, self-esteem and autonomy; and a sense of belonging and increased social integration. A recent review of older people's (including those living with dementia) sensory engagement with nature found that older people derived considerable pleasure and enjoyment from viewing nature, being and doing in nature which, in turn had a positive impact on their wellbeing and quality of life.¹²

The evidence suggests that:

- CST is an effective intervention that is acceptable to people living with dementia;
- Engaging with nature can be beneficial for people living with dementia.

It would seem reasonable to suggest that a nature-based CST intervention could potentially be acceptable to people living with dementia but it has not been researched.

Ongoing studies/ Trials in progress: No ongoing studies assessing nature-based CST for people living with mild to moderate dementia were found.

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: Dementia is recognised as one of the biggest global health and social care challenges. There are 850,000 people living with dementia in the UK, with over 700,000 in England and over 81,000 in the South West, and it is predicted this figure will rise to over 106,000 by 2021.¹³

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Dementia costs the UK economy over £24 billion a year and by 2025 it is expected that it will cost £32.5 billion.¹³

The potential for health improvement: People living with dementia must deal not only with the issues associated with the disease, such as memory loss, loss of balance and alterations in personality but with ‘by-products’ of a diagnosis such as increases in anxiety, depression, social isolation, loneliness, and social stigma. Although there is no cure for dementia, living well with dementia is a recent UK government priority and arguably, being able to access and enjoy the natural environment should be part of what the ‘good life’ with dementia looks like. Yet the existing evidence suggests that a significant proportion of people with dementia do not have regular contact with nature: 50% of care home residents with dementia never go outside, and a further 25% go outdoors only rarely.¹⁴ More than two-thirds of community-dwelling people with dementia reported that they have ceased participation in activities they formerly enjoyed, due to a loss of confidence and a fear of becoming lost or confused. Consequently, 50% of people with dementia leave the house only once a week or less, resulting in reduced opportunities to benefit from interaction with the outdoors.¹⁵ A nature-based CST programme has the potential to enable individuals to remain meaningfully engaged in their lives and surroundings.

The practicality of the research question: Nature-based CST is delivered at the Sydenham Garden *Sow and Grow* project in London and the Sensory Trust, a charity based in Cornwall, has also piloted a small project in partnership with Memory Matters South West, whereby one group received nature-based CST, devised by Sensory Trust and integrating nature-based activities into the established CST themes. For example, the Numbers activity was based on the Fibonacci sequences in nature. A control group received the non-nature CST at the same time. The results showed improved cognition for both groups but the trial was too small to definitively demonstrate that the integration of nature improved cognition and quality of life. However, it did appear that those who participated in nature-based CST had similar improvement in cognition as the members of the control group.¹⁶

Whether the South West is a good place to do this research: The Sensory Trust in Cornwall is committed to using nature and the outdoors to improve the health and wellbeing of people living with disability and health issues. In addition to piloting the project described above, the Sensory Trust has led a flagship dementia project, *Creative Spaces*, which supported people living with dementia and their carers to participate in nature-based activities and community walks. The Sensory Trust work throughout the UK and shares its work with a wide network of organisations and individuals.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

Department of Health (2009) *Living well with dementia. A national dementia strategy*. London: Department of Health.

HM Government (2011) *The natural choice: securing the value of nature*. London: The Stationery Office.

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National Collaborating Centre for Mental Health (2007) *Dementia: the NICE-SCIE guidelines on supporting people with dementia and their carers in health and social care*. London: The British Psychological Society and Gaskell.

'Non-pharmacological interventions for cognitive symptoms and maintaining function

1.6.1.1 People with mild-to-moderate dementia of all types should be given the opportunity to participate in a structured group cognitive stimulation programme. This should be commissioned and provided by a range of health and social care staff with appropriate training and supervision, and offered irrespective of any drug prescribed for the treatment of cognitive symptoms of dementia' (p. 25).

Relevant Abstracts:

Toh, H. M. Ghazali, S. E. and Subramaniam, P. The acceptability and usefulness of Cognitive Stimulation Therapy for older adults with dementia: a narrative review. *International Journal of Alzheimer's Disease* 2016 Article ID 5131570

Abstract: Cognitive stimulation therapy (CST) is an evidence-based therapy for individuals with mild-to-moderate dementia. Past reviews have only synthesized outcomes obtained through quantitative study which does not fully represent the understanding on the acceptability and usefulness of CST. Therefore, the present review aims to integrate outcomes obtained from both quantitative and qualitative studies to provide a deeper understanding on the acceptability and usefulness of CST for older adults with dementia. Findings of literature were retrieved from searches of computerized databases in relation to CST for people with dementia. Literatures were selected according to selection criteria outlined. Results obtained in previous studies pertaining to the effects of CST were discussed in relation to variables such as cognitive function, quality of life, and family caregivers' wellbeing. The review also explores the use of CST in different cultural context, the perception on its effectiveness, and individualized CST (iCST). There is considerable evidence obtained through quantitative and qualitative studies on the usefulness and acceptability of CST for older adults with dementia. Recommendations for future research are provided to strengthen the evidence of CST's effectiveness.

Woods, B., Aguirre, E., Spector, A. E. & Orrell, M. (2012) Cognitive stimulation to improve functioning in people with dementia. *Cochrane Databases of Systematic Reviews* Issue 2. Art. No.: CD005562.

Background: Cognitive stimulation is an intervention for people with dementia which offers a range of enjoyable activities providing general stimulation for thinking, concentration and memory usually in a social setting, such as a small group. Its roots can be traced back to Reality Orientation (RO), which was developed in the late 1950s as a response to confusion and disorientation in older patients in hospital units in the USA. RO emphasised the engagement of nursing assistants in a hopeful, therapeutic process but became associated with a rigid, confrontational approach to people with dementia, leading to its use becoming less and less common. Cognitive stimulation is often discussed in normal ageing as well as in dementia. This reflects a general view that lack of cognitive activity hastens cognitive decline. With people with dementia, cognitive stimulation attempts to make use of the positive aspects of RO whilst ensuring that the stimulation is implemented in a sensitive, respectful and person-centred manner. There is often little consistency in the application and availability of psychological therapies in dementia

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services, so a systematic review of the available evidence regarding cognitive stimulation is important in order to identify its effectiveness and to place practice recommendations on a sound evidence base.

Objectives: To evaluate the effectiveness and impact of cognitive stimulation interventions aimed at improving cognition for people with dementia, including any negative effects.

Search methods: The trials were identified from a search of the Cochrane Dementia and Cognitive Improvement Group Specialized Register, called ALOIS (updated 6 December 2011). The search terms used were: cognitive stimulation, reality orientation, memory therapy, memory groups, memory support, memory stimulation, global stimulation, cognitive psychostimulation. Supplementary searches were performed in a number of major healthcare databases and trial registers to ensure that the search was up to date and comprehensive.

Selection criteria: All randomised controlled trials (RCTs) of cognitive stimulation for dementia which incorporated a measure of cognitive change were included.

Data collection and analysis: Data were extracted independently by two review authors using a previously tested data extraction form. Study authors were contacted for data not provided in the papers. Two review authors conducted independent assessments of the risk of bias in included studies.

Main results: Fifteen RCTs were included in the review. Six of these had been included in the previous review of RO. The studies included participants from a variety of settings, interventions that were of varying duration and intensity, and were from several different countries. The quality of the studies was generally low by current standards but most had taken steps to ensure assessors were blind to treatment allocation. Data were entered in the meta-analyses for 718 participants (407 receiving cognitive stimulation, 311 in control groups). The primary analysis was on changes that were evident immediately at the end of the treatment period. A few studies provided data allowing evaluation of whether any effects were subsequently maintained. A clear, consistent benefit on cognitive function was associated with cognitive stimulation (standardised mean difference (SMD) 0.41, 95% CI 0.25 to 0.57). This remained evident at follow-up one to three months after the end of treatment. In secondary analyses with smaller total sample sizes, benefits were also noted on self-reported quality of life and well-being (standardised mean difference: 0.38 [95% CI: 0.11, 0.65]); and on staff ratings of communication and social interaction (SMD 0.44, 95% CI 0.17 to 0.71). No differences in relation to mood (self-report or staff-rated), activities of daily living, general behavioural function or problem behaviour were noted. In the few studies reporting family caregiver outcomes, no differences were noted. Importantly, there was no indication of increased strain on family caregivers in the one study where they were trained to deliver the intervention.

Authors' conclusions: There was consistent evidence from multiple trials that cognitive stimulation programmes benefit cognition in people with mild to moderate dementia over and above any medication effects. However, the trials were of variable quality with small sample sizes and only limited details of the randomisation method were apparent in a number of the trials. Other outcomes need more exploration but improvements in self-reported quality of life and well-being were promising. Further research should look into the potential benefits of longer term cognitive stimulation programmes and their clinical significance.

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The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days. The briefing is in four parts:

- i. General context
- ii. The question in a research format
- iii. What the research evidence says
- iv. Alignment with PenCLAHRC research priority criteria

QUESTION: Does provision of information about the true cost of drugs at the time of prescribing or dispensing impact on medicines wastage or have unintended consequences?

General context and definitions: The gross annual cost of NHS primary and community care prescription medicines wastage in England is thought to be in the order of £300 million per year. This figure includes an estimated £90 million worth of unused prescription medicines that are retained in individuals' homes at any one time, £110 million returned to community pharmacies over the course of a year, and £50 million worth of NHS supplied medicines that are disposed of unused by care homes. Medicines wastage can occur through five avenues:

- Non Compliance – patient does not take medicines as prescribed.
- Intentional Non Adherence – patient stops taking medicines due to adverse side effects or personal beliefs.
- Unintentional Non Adherence – patient stops taking medicines, or fails to take at correct intervals due to forgetfulness.
- Non-Preventable Waste – patient dies and unused medicines are wasted, or a change in treatment means current dispensed medicines are no longer required.
- Preventable Waste – patient stock piles medicines “just in case” (1).

The question in a structured format: In considering this as a research question, we could frame it as:

<i>Population:</i>	People receiving regular prescribed medication (or long courses of medication) that they may or may not use as directed.
<i>Intervention:</i>	Providing the patient with information about the cost to the NHS of medication at the time and the importance of ensuring they take their medication as directed or return to the prescriber if they have queries or concerns about their medication rather than stopping it or changing the dose.
<i>Comparator:</i>	Patient receiving standard care and advice (no information on cost to the NHS)
<i>Outcomes of Interest:</i>	<u>Service outcomes</u> - Medicines wastage (prescription without use) <u>Process outcomes</u> – Time to deliver information, mode of information, patient understanding. Barriers and facilitators to approach <u>Patient outcomes</u> – appropriate use of medicines, awareness of costs and importance of using medicines as directed, how does information affect behaviour/thought processes about using medication?, confidence in the service and returning to prescriber with queries?

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What the research evidence says: Two systematic reviews were identified that might inform this uncertainty, though the data for these reviews largely comes from the US and Canada. Allan et al's (2007) review looked at the role of physician awareness of medication costs and the potential impact it may have on prescribing. They found that doctors want cost information but that it is not always available, that doctors primarily underestimate the cost of expensive medication and overestimate the cost of inexpensive medication, and report a need for more research into how medication cost information is provided to doctors and if it really makes a difference to prescribing (2). These findings may also have implications for then being able to provide this information to patients. Another review conducted in 2015 looks at physician-patient communication of healthcare costs in the US (3). They report that although both the physician and the patient rate cost information as important to know and discuss, conversations about costs rarely happen. Some of the barriers include awareness of the costs and lack of resources, and time and training to communicate healthcare costs to the patient. (Please note a third non-systematic review was also found looking the physician-patient communication of treatment costs in oncology care (4) but the poor reporting of the review restricts the sense of its reliability and usefulness for the purposes of this briefing).

Five primary studies were found: two (5, 6) of which were based on UK data and included in the 2007 review (2). Since then three other studies have been conducted, two based in the US (7, 8) and one in the UK (9) (see abstracts below). All three studies suggest the knowledge and discussion of treatment costs could be beneficial for the health system and the patient but they also report that much is currently unknown including the influence of different costing systems, how best to have these discussions or share appropriate cost information, and the ethics behind introducing this information into patient care decisions particularly in systems which are designed to use only necessary treatment options.

The '*Evaluation of the Scale, Causes and Costs of Waste Medicines*' joint report from School of Pharmacy and York Economics Consortium (2010) provides limited qualitative data about user perception of medicine cost. There is considerable good quality published research on reducing medicines wastage through restricting prescription length, conducting medication reviews, use of patients' own drugs (PODs) and repeat dispensing schemes. Other novel interventions such as 'medicines recycling' to reduce waste have also been published as primary research in the past two years.

Ongoing studies/ Trials in progress:

No ongoing trials found.

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: The gross annual cost of NHS primary and community care prescription medicines wastage in England is thought to be in the order of £300 million per year. Costs in Devon are estimated to be around £5.5million, in Cornwall around £3million and in Somerset around £3million.

The potential for health improvement: The potential for health improvement is currently unknown with little UK published research that looks at the impact on health outcomes for patients as well as financial impact for patients and the health service and the way in which cost information should be

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communicated. There are some suggestions that health could be improved by encouraging patients to take their medicine as prescribed or by encouraging patients to discuss concerns about medication with their GP.

The practicality of the research question: Different strategies to reduce medicine wastage have been initiated around the country. Sharing treatment cost information initiatives will need to agree exactly what and how information is communicated (thereby agreeing the ethics behind these discussions) and who the information is to be targeted at (GP, Patient, or pharmacist).

Whether the South West is a good place to do this research: A pilot study has recently (2016) been conducted in GP practices in Torbay and South Devon trialling a system whereby patients request their own repeat prescriptions rather than them being automatically repeated after 28 days. There are no clear reasons why the South West would not be an appropriate location for this research.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

NHS England (2015) produces a report (1) summarising the context of medicines waste in England. The report also identifies a number of case studies which have looked at different strategies of encouraging medicines waste reduction conducted by CCGs throughout England. These case studies have occurred largely within the care home setting but one case study looks at repeat prescribing in primary care and another looks at a medicines waste campaign across primary, secondary and community care including pharmacists. The findings of these case studies have identified some common themes for best practice:

- Support at point of prescribing – intervention at the point of prescribing to ensure the correct medication and correct dosage is being prescribed and that the patient fully understands the way in which the medicines should be taken to achieve the best health outcomes.
- Control of medicine optimisation – conducting a review of medicines at regular intervals to avoid unnecessary dispensing and to ensure any changes in patient symptoms are reflected in changes to medication.
- Benefits – any project or scheme that is successful must understand the current state of waste and be able to track the benefits throughout the life of the project and beyond. Being able to highlight and demonstrate benefits (e.g. preventing harmful non-adherence, medicines optimisation where medicines have been optimised causing a health benefit to the patient and a financial benefit to the CCG) are key to ensuring a project can transition into ‘business as usual’, making long-term changes rather than disappearing as a one off piece of work.
- Governance & Knowledge – intervention from competent and knowledgeable people with the skills to optimise medicines and increase efficiencies. Utilising pharmacist knowledge in the monitoring of repeat prescriptions, with the ability to inform and educate patients and care home staff with the goal of changing culture.
- Communication – effective communication has been seen where multi-disciplinary teams have been able to communicate both internally to create an efficient team, but also with external stakeholders.

In 2015 Jeremy Hunt also stated that ‘we intend to publish the indicative medicine costs to the NHS on the packs of all medicines costing more than £20, which will also be marked ‘funded by the UK

taxpayer'. This will not just reduce waste by reminding people of the cost of medicine, but also improve patient care by boosting adherence to drug regimes. I will start the processes to make this happen this year, with an aim to implement it next year.' But it is unclear if this initiative has been rolled out. (<https://www.gov.uk/government/speeches/personal-responsibility>)

Relevant Abstracts:

2007 G. M. Allan, J. Lexchin and N. Wiebe; Physician awareness of drug cost: a systematic review. PLoS medicine 4, e283

BACKGROUND: Pharmaceutical costs are the fastest-growing health-care expense in most developed countries. Higher drug costs have been shown to negatively impact patient outcomes. Studies suggest that doctors have a poor understanding of pharmaceutical costs, but the data are variable and there is no consistent pattern in awareness. We designed this systematic review to investigate doctors' knowledge of the relative and absolute costs of medications and to determine the factors that influence awareness., **METHODS AND FINDINGS:** Our search strategy included The Cochrane Library, EconoLit, EMBASE, and MEDLINE as well as reference lists and contact with authors who had published two or more articles on the topic or who had published within 10 y of the commencement of our review. Studies were included if: either doctors, trainees (interns or residents), or medical students were surveyed; there were more than ten survey respondents; cost of pharmaceuticals was estimated; results were expressed quantitatively; there was a clear description of how authors defined "accurate estimates"; and there was a description of how the true cost was determined. Two authors reviewed each article for eligibility and extracted data independently. Cost accuracy outcomes were summarized, but data were not combined in meta-analysis because of extensive heterogeneity. Qualitative data related to physicians and drug costs were also extracted. The final analysis included 24 articles. Cost accuracy was low; 31% of estimates were within 20% or 25% of the true cost, and fewer than 50% were accurate by any definition of cost accuracy. Methodological weaknesses were common, and studies of low methodological quality showed better cost awareness. The most important factor influencing the pattern and accuracy of estimation was the true cost of therapy. High-cost drugs were estimated more accurately than inexpensive ones (74% versus 31%, Chi-square $p < 0.001$). Doctors consistently overestimated the cost of inexpensive products and underestimated the cost of expensive ones (binomial test, 89/101, $p < 0.001$). When asked, doctors indicated that they want cost information and feel it would improve their prescribing but that it is not accessible., **CONCLUSIONS:** Doctors' ignorance of costs, combined with their tendency to underestimate the price of expensive drugs and overestimate the price of inexpensive ones, demonstrate a lack of appreciation of the large difference in cost between inexpensive and expensive drugs. This discrepancy in turn could have profound implications for overall drug expenditures. Much more focus is required in the education of physicians about costs and the access to cost information. Future research should focus on the accessibility and reliability of medical cost information and whether the provision of this information is used by doctors and makes a difference to physician prescribing. Additionally, future work should strive for higher methodological standards to avoid the biases we found in the current literature, including attention to the method of assessing accuracy that allows larger absolute estimation ranges for expensive drugs.

2015 A. L. Meluch and W. H. Oglesby; Physician-patient communication regarding patients' healthcare costs in the US: A systematic review of the literature. Journal of Communication in Healthcare,8,151-160

Background/objectives The increasing cost of healthcare is a major issue for US policymakers and patients and their families. To date, little research has focused on physician-patient communication about healthcare costs. This systematic review identifies themes present in that literature and synthesizes findings. **Methods** PubMed, CINAHL, PsycINFO, and Communication and Mass Media

Complete were searched to identify articles regarding physician–patient communication about healthcare costs. The search yielded 24 articles based on inclusion criteria. Results Empirical findings showed that most physicians and patients were open to discussion about costs; however, few actual conversations were reported across research studies. Most of the research on physician–patient communication about healthcare costs explored issues of non-adherence and identified relevant communication barriers. Research on physician–patient communication about healthcare costs currently lacks evidence-based strategies for increasing and improving these discussions. Conclusions Physicians and patients judge communication about healthcare costs to be important and to have the potential to influence health and financial outcomes; however, discussions between physicians and patients on the topic are rare.

2010 E. W. Hofstatter; Understanding patient perspectives on communication about the cost of cancer care: A review of the literature. *Journal of Oncology Practice*, 6, 188-192

Purpose: Patient-physician communication about cost when making treatment decisions has been promoted as a potential solution to the rising cost of oncologic care and suggested as an important component of high-quality oncologic care. However, little is known regarding the perspectives of patients with cancer on such discussions with their physicians. Methods: A literature review was performed in July 2009, with search terms including but not limited to patient-physician communication, cost of cancer care, and cost communication. Results: The cost of cancer care is high and seems to affect decisions that many patients make about the treatment they receive. Yet there is scant oncology literature on patient-physician cost communication, with the only formal study examining oncologist perspectives. Extrapolation from the general medicine literature may not be appropriate for this unique population of patients, and there are some data to suggest that patients with cancer may prefer not to discuss finances with their oncologists. Practical guidelines and tools for discussions of cost with patients with cancer are also limited. Conclusion: To my knowledge, patient preferences surrounding discussion of cost of cancer care have gone largely unstudied and are thus unknown. If the goal is to provide highquality care while controlling rising health care costs, more research is needed to better understand patient perspectives on communication surrounding the cost of oncologic care, particularly given the significant impact such discussions may have on cancer outcomes, cost, and overall patient satisfaction.

2015 J. S. Blumenthal-Barby, E. Robinson, S. B. Cantor, A. D. Naik, H. V. Russell and R. J. Volk; The neglected topic: presentation of cost information in patient decision AIDS. *Medical decision making : an international journal of the Society for Medical Decision Making*, 35, 412-8

Costs are an important component of patients' decision making, but a comparatively underemphasized aspect of formal shared decision making. We hypothesized that decision aids also avoid discussion of costs, despite their being tools designed to facilitate shared decision making about patient-centered outcomes. We sought to define the frequency of cost-related information and identify the common modes of presenting cost and cost-related information in the 290 decision aids catalogued in the Ottawa Hospital Research Institute's Decision Aid Library Inventory (DALI) system. We found that 56% (n = 161) of the decision aids mentioned cost in some way, but only 13% (n = 37) gave a specific price or range of prices. We identified 9 different ways in which cost was mentioned. The most common approach was as a "pro" of one of the treatment options (e.g., "you avoid the cost of medication"). Of the 37 decision aids that gave specific prices or ranges of prices for treatment options, only 2 were about surgery decisions despite the fact that surgery decision aids were the most common. Our findings suggest that presentation of cost information in decision aids is highly variable. Evidence-based guidelines should be developed by the International Patient Decision Aid Standards (IPDAS) Collaboration. Copyright © The Author(s) 2015.

2014 J. Y. Chan and T. Butt; Does Price Matter? The Impact of Cost Information On Patient Decision Making. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research, 17, A516

In publicly funded health systems such as the United Kingdom (UK) National Health service (NHS), patients do not normally face the full economic cost of treatment decisions, nor are they aware of the cost to the system. Decision aids help patients to make informed choices by presenting evidence-based information in a format that makes it easier for patients and healthcare professionals to discuss treatment options as part of the shared decision making process. The primary objective of this study was to investigate whether patient awareness of treatment costs presented alongside condition-specific decision aids influences treatment decisions. The secondary objective was to investigate whether cost perspective affects patient decision making.

2014 J. F. Kruger, A. H. Chen, A. Rybkin, K. Leeds, D. L. Frosch and E. Goldman; Clinicians' views on displaying cost information to increase clinician cost-consciousness. The American journal of managed care, 20, 901-6

OBJECTIVES: To evaluate 1) clinician attitudes towards incorporating cost information into decision making when ordering imaging studies; and 2) clinician reactions to the display of Medicare reimbursement information for imaging studies at clinician electronic order entry., STUDY DESIGN: Focus group study with inductive thematic analysis., METHODS: We conducted focus groups of primary care clinicians and subspecialty physicians (nephrology, pulmonary, and neurology) (N = 50) who deliver outpatient care in 12 hospital-based clinics and community health centers in an urban safety net health system. We analyzed focus group transcripts using an inductive framework to identify emergent themes and illustrative quotations., RESULTS: Clinicians believed that their knowledge of healthcare costs was low and wanted access to relevant cost information for reference. However, many clinicians believed it was inappropriate and unethical to consider costs in individual patient care decisions. Among clinicians' negative reactions toward displaying costs at order entry, 4 underlying themes emerged: 1) belief that ordering is already limited to clinically necessary tests; 2) importance of prioritizing responsibility to patients above that to the healthcare system; 3) concern about worsening healthcare disparities; and 4) perceived lack of accountability for healthcare costs in the system., CONCLUSIONS: Although clinicians want relevant cost information, many voiced concerns about displaying cost information at clinician order entry in safety net health systems. Alternative approaches to increasing cost-consciousness may be more acceptable to clinicians.

2002 E. I. Schafheutle, K. Hassell, P. R. Noyce and M. C. Weiss; Access to medicines: cost as an influence on the views and behaviour of patients. Health & Social Care in the Community, 10, 187-195

The present paper explores how charges for medicines incurred by patients influence their decisions for managing acute or chronic conditions, and whether prescription cost and affordability issues are discussed in the general practitioner (GP)-patient encounter. People suffering from dyspepsia, hay fever or hypertension, or those taking hormone replacement therapy, were recruited through three community pharmacies in the Northwest of England. Six focus groups were conducted with a total of 31 participants, the majority of whom were non-exempt from prescription charges. The management behaviour of those participants who had to pay for their prescriptions, particularly those from less-affluent or deprived backgrounds, was influenced by cost. However, cost was not the overriding influence, with other factors, such as symptom or disease severity, effectiveness, or necessity of treatment, playing a more important part in participants' management decisions. Cost as an issue was reflected in the various strategies used by participants to reduce medication cost, such as not having some prescribed items dispensed, taking a smaller dose or buying a cheaper over-the-counter product. Despite the use of numerous strategies, participants did not talk to their GPs about issues of cost and affordability. Participants felt that paying for prescriptions was their problem. There was a belief that discussing cost issues could jeopardise the doctor-patient relationship. Although not the dominant factor, medication cost nevertheless influenced participants when deciding how to manage their condition. Awareness of the existence of prepayment certificates, which can be bought by patients who

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require regular medication, was low, and this should be addressed through improved information/dissemination. Despite the high level of prescription items exempt, the current level of the prescription charge is still a barrier to obtaining prescription medicines under the National Health Service to those on lower incomes.

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- ii. The question in a research format
- iii. What the research evidence says
- iv. Alignment with PenCLAHRC research priority criteria

QUESTION: Does employment support, within IAPT services, improve mental health and employment outcomes for individuals with common mental health problems who are either at work, off sick or out of work?

General context and definitions: *Improving Access to Psychological Therapies* (IAPT) is an NHS initiative that aims to increase the availability of NICE recommended psychological treatment for depression and anxiety disorders in England. Much of the original argument for establishing the programme was based on the expected economic and social benefits arising from improving people’s economic status as well as their symptoms. It was argued that the service would pay for itself by reducing depression and anxiety-related public costs (welfare benefits and medical care) and increasing revenues (taxes from return to work and increased productivity). As a result, the national training curriculum incorporated a number of learning outcomes designed to ensure that Psychological Wellbeing Workers delivering low impact IAPT had knowledge of and competence in liaison and signposting to agencies delivering employment and occupational advice and services.

There are currently approximately 200 IAPT services in the UK delivered by a range of providers. The nature of employment support is not defined or standardised. Information on how employment support is provided is not readily available but appears to differ between regions and teams in terms of both the people delivering it (employment support workers who are part of the IAPT service or members of external organisations) and where it is delivered (in the same location as the IAPT service or not).

The question in a structured format: In considering this as a research question, we could frame it as:

<i>Population:</i>	Individuals with common mental health problems attending IAPT services who are at work, off sick or out of work
<i>Intervention:</i>	Employment support provided within IAPT services
<i>Comparator:</i>	Usual care
<i>Outcomes of Interest:</i>	Mental health symptoms, time off work, time to returning to work, time to obtaining work

What the research evidence says: A Cochrane review published in 2014¹ assessed the effectiveness of interventions aimed at reducing work disability in employees with depressive disorders. The review concluded that adding a work-directed intervention to a clinical intervention reduces the number of days on sick leave compared to a clinical intervention alone. This suggests that adding a work-directed intervention to a clinical intervention has the potential to reduce sickness absence. The review highlighted the heterogeneity in existing studies and suggested that future clinical intervention studies

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should also include work outcomes to increase knowledge of reducing sickness absence in workers with depression.

In 2009, an Employment Adviser pilot programme was introduced in 11 areas in England – and later at sites in Scotland and Wales – with the aim of testing the added value of providing employment advice as well as psychological therapy to employed IAPT clients to help them remain at work or return to work if on sick leave². Problems that prompted IAPT service users to seek employment advice were often associated with relationship difficulties with their managers and colleagues, the reorganisation of work, and difficulties managing workloads. Of those who were attending work when they first saw an employment adviser, 84% were still attending work when they stopped seeing their advisor. Of those in employment off work sick on first seeing an adviser, 63% had resumed attendance at work when they stopped seeing an advisor and nine per cent were still in employment but remained off sick (the remaining 29 per cent had left employment and were unemployed, permanently sick/disabled, retired or otherwise economically inactive). Client perceptions of the service were positive – 89% of clients would recommend the employment adviser service to others and 58% said that their problems at work had been partially or fully resolved by seeing an adviser. However, it is not clear from the data collected, how much of the impact of the programme can be attributed to the IAPT service alone as there were difficulties in obtaining data for a robust comparator group.

An assessment of the economic impact of the Working for Wellness Employment Support Service delivered as part of the IAPT service in London concluded that for every £1 spent, £2.79 is generated in benefits (of which 84p benefits the individual and £1.95 benefits the state)³.

The IAPT Annual report does not include data on employment outcomes⁴.

Individual placement and support (IPS) is a carefully specified form of employment support. A Cochrane Review in which supported employment and IPS were compared with other approaches for finding employment identified 14 studies involving a total of 2259 people with severe mental health problems⁵. The review had two main findings: 1) Supported employment increases the length and time of people's employment; 2) People on supported employment find jobs quicker. Supported employment and IPS are better than other approaches in these two respects, but there is limited information or measurable differences on other important issues for service users. A small-scale feasibility pilot service offering IPS with IAPT was run in 2014 in four sites in England, however the available results are concerned with the practicalities of running the service rather than the effectiveness of the approach⁶.

We identified no evidence to inform the identification of essential components of employment support, or how it can best be embedded in IAPT services.

Ongoing studies/ Trials in progress:

No ongoing trials found.

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: Over 900,000 people now access IAPT every year in the UK. Stable employment is an important contributing factor to someone being able to maintain good mental health. Figures cited in the Five Year Forward View for Mental Health suggest that only 43% of adults

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with mental health problems are in employment compared to 74% of the general population and 65% of people with other health conditions.

The potential for health improvement: Stable employment is an important contributing factor to someone being able to maintain good mental health.

The practicality of the research question: PenCLAHRC conducted an evaluation of IAPT services in the South West in 2011⁷. In this evaluation 23% of new referrals to IAPT were unemployed. Further work to survey the different employment support models in IAPT services in the Southwest is ongoing and four services, to date, have expressed an interest in collaborating to achieve this.

Whether the South West is a good place to do this research: As in other parts of the UK, there is variation in the way that IAPT is delivered across the South West and in the way that employment support is provided.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

The Five Year Forward Plan for Mental Health: A report from the independent Mental Health Taskforce to the NHS in England (February 2016). The Five Year Forward Plan for Mental Health is an independent report from the Mental Health Taskforce that sets out the start of a ten year journey to transform mental health care in the NHS. Employment is acknowledged as being vital to health and it is recommended that it be recognised as a health outcome. The document states that the NHS must play a greater role in supporting people to find or keep a job.

Specific relevant recommendations are:

Recommendation 5: By 2020/21, each year up to 29,000 more people living with mental health problems should be supported to find or stay in work through increasing access to psychological therapies for common mental health problems and expanding access to Individual Placement and Support (IPS). The Department of Work and Pensions should also invest to ensure that qualified employment advisers are fully integrated into expanded psychological therapies services.

Recommendation 6: The Department of Health and the Department for Work and Pensions, working with NHS England and PHE, should identify how the £40 million innovation fund announced at the Spending Review and other investment streams should be used to support devolved areas to jointly commission more services that have been proven to improve mental health and employment outcomes, and test how the principles of these services could be applied to other population groups and new funding mechanisms (e.g. social finance).

Recommendation 7: The Department for Work and Pensions should ensure that when it tenders the Health and Work Programme it directs funds currently used to support people on Employment Support Allowance to commission evidence-based health-led interventions that are proven to deliver improved employment outcomes – as well as improved health outcomes – at a greater rate than under current Work Programme contracts.

Van Stolk C, Hofman J, Hafner M, Janta B (2014) *Psychological Wellbeing and Work Improving Service Provision and Outcomes* published by the Department for Work and Pensions and the Department of Health

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The key messages from this report are:

- The assessment of employment and health needs of people with mental health problems is difficult and there are low rates of diagnosis or referral to specialist health and employment support;
- The services often work in isolation and tackle either the mental health problem or the employment need discretely; addressing both is important as there is no systematic evidence that better health treatment alone will deliver employment outcomes;
- Service provision is often delayed and both health and employment problems can worsen as a result, whereas early access is important to prevent people from falling out of work or bringing them back into work;
- Although there is some evidence for what works to help employees retain work when mental health problems arise, evidence of what works for people in the benefit system is limited;
- The interaction between mental health and employment is complex and unlikely to lend itself to a “one size fits all” solution.

A longlist of policy options was generated for the Government to consider. They include workplace interventions, influencing the behaviour of key gatekeepers, improving assessments of employment and wellbeing needs of people with common mental health problems, building up employment advice in current programmes, and more.

Four shortlisted options propose models of service delivery that:

- Provide earlier access to specialist services;
- Address both employment and mental health needs; and
- Introduce more integration between current services or propose new or innovative applications of existing evidence-based models.

Option 1: Embed vocational support based on the Individual Placement and Support (IPS) model in primary care settings. The key principles of IPS are specified and the model has been tested in secondary care settings for people with severe mental illness. This intervention would be accessed through services offering psychological therapy or even through GP practices.

Option 2: Use group work in employment services to build self-efficacy and resilience to setbacks that benefit claimants face when job seeking. This intervention would be based on the JOBS II programme that has been tested in several countries but not yet in the UK. It would be accessed through Jobcentre Plus but delivered in neutral settings.

Option 3: Provide access to online mental health and work assessment and support. This intervention would build on models of online mental health assessment and Cognitive Behavioural Therapy (that have been tested). It would include a vocational element, which would have to be developed, and it could be open to the general population.

Option 4: Jobcentre Plus commissions third parties to provide a telephone-based specialist psychological and employment-related support. Telephone based services offered through this intervention would be very similar to the support provided by Employee Assistance Programmes and models designed for the Work Programme. It would be offered accessed through Jobcentre Plus. 5.

Relevant Abstracts:

Kinoshita Y(1), Furukawa TA, Kinoshita K, Honyashiki M, Omori IM, Marshall M, Bond GR, Huxley P, Amano N, Kingdon D. Supported employment for adults with severe mental illness. Cochrane Database Syst Rev. 2013 Sep 13;(9):CD008297. doi: 10.1002/14651858.CD008297.pub2.

BACKGROUND: People who suffer from severe mental disorder experience high rates of unemployment. Supported employment is an approach to vocational rehabilitation that involves trying to place clients in competitive jobs without any extended preparation. The Individual placement and support (IPS) model is a carefully specified form of supported employment.

OBJECTIVES: To review the effectiveness of supported employment compared with other approaches to vocational rehabilitation or treatment as usual. Secondary objectives were to establish how far:(a) fidelity to the IPS model affects the effectiveness of supported employment,(b) the effectiveness of supported employment can be augmented by the addition of other interventions.

SEARCH METHODS: We searched the Cochrane Schizophrenia Group Trials Register (February 2010), which is compiled by systematic searches of major databases, handsearches and conference proceedings.

SELECTION CRITERIA: All relevant randomised clinical trials focusing on people with severe mental illness, of working age (normally 16 to 70 years), where supported employment was compared with other vocational approaches or treatment as usual. Outcomes such as days in employment, job stability, global state, social functioning, mental state, quality of life, satisfaction and costs were sought.

DATA COLLECTION AND ANALYSIS: Two review authors (YK and KK) independently extracted data. For binary outcomes, we calculated risk ratio (RR) and its 95% confidence interval (CI), on an intention-to-treat basis. For continuous data, we estimated mean difference (MD) between groups and its 95% (CI). We employed a fixed-effect model for analyses. A random-effects model was also employed where heterogeneity was present.

MAIN RESULTS: A total of 14 randomised controlled trials were included in this review (total 2265 people). In terms of our primary outcome (employment: days in competitive employment, over one year follow-up), supported employment seems to significantly increase levels of any employment obtained during the course of studies (7 RCTs, n = 951, RR 3.24 CI 2.17 to 4.82, very low quality of evidence). Supported employment also seems to increase length of competitive employment when compared with other vocational approaches (1 RCT, n = 204, MD 70.63 CI 43.22 to 94.04, very low quality evidence). Supported employment also showed some advantages in other secondary outcomes. It appears to increase length (in days) of any form of paid employment (2 RCTs, n = 510, MD 84.94 CI 51.99 to 117.89, very low quality evidence) and job tenure (weeks) for competitive employment (1 RCT, n = 204, MD 9.86 CI 5.36 to 14.36, very low quality evidence) and any paid employment (3 RCTs, n = 735, MD 3.86 CI -2.94 to 22.17, very low quality evidence). Furthermore, one study indicated a decreased time to first competitive employment in the long term for people in supported employment (1 RCT, n = 204, MD -161.60 CI -225.73 to -97.47, very low quality evidence). A large amount of data were considerably skewed, and therefore not included in meta-analysis, which makes any meaningful interpretation of the vast amount of data very difficult.

AUTHORS' CONCLUSIONS: The limited available evidence suggests that supported employment is effective in improving a number of vocational outcomes relevant to people with severe mental illness, though there appears to exist some overall risk of bias in terms of the quality of individual studies. All studies should report a standard set of vocational and non-vocational outcomes that are relevant to the consumers and policy-makers. Studies with longer follow-up should be conducted to answer or address the critical question about durability of effects.

Nieuwenhuijsen K(1), Faber B, Verbeek JH, Neumeyer-Gromen A, Hees HL, Verhoeven AC, van der Feltz-Cornelis CM, Bültmann U. Interventions to improve return to work in depressed people Cochrane Database Syst Rev. 2014 Dec 3;(12):CD006237. doi: 10.1002/14651858.CD006237.pub3.

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BACKGROUND: Work disability such as sickness absence is common in people with depression.

OBJECTIVES: To evaluate the effectiveness of interventions aimed at reducing work disability in employees with depressive disorders.

SEARCH METHODS: We searched CENTRAL (The Cochrane Library), MEDLINE, EMBASE, CINAHL, and PsycINFO until January 2014.

SELECTION CRITERIA: We included randomised controlled trials (RCTs) and cluster RCTs of work-directed and clinical interventions for depressed people that included sickness absence as an outcome.

DATA COLLECTION AND ANALYSIS: Two authors independently extracted the data and assessed trial quality. We used standardised mean differences (SMDs) with 95% confidence intervals (CIs) to pool study results in the studies we judged to be sufficiently similar. We used GRADE to rate the quality of the evidence.

MAIN RESULTS: We included 23 studies with 26 study arms, involving 5996 participants with either a major depressive disorder or a high level of depressive symptoms. We judged 14 studies to have a high risk of bias and nine to have a low risk of bias. Work-directed interventions. We identified five work-directed interventions. There was moderate quality evidence that a work-directed intervention added to a clinical intervention reduced sickness absence (SMD -0.40; 95% CI -0.66 to -0.14; 3 studies) compared to a clinical intervention alone. There was moderate quality evidence based on a single study that enhancing the clinical care in addition to regular work-directed care was not more effective than work-directed care alone (SMD -0.14; 95% CI -0.49 to 0.21). There was very low quality evidence based on one study that regular care by occupational physicians that was enhanced with an exposure-based return to work program did not reduce sickness absence compared to regular care by occupational physicians (non-significant finding: SMD 0.45; 95% CI -0.00 to 0.91). Clinical interventions, antidepressant medication. Three studies compared the effectiveness of selective serotonin reuptake inhibitor (SSRI) to selective norepinephrine reuptake inhibitor (SNRI) medication on reducing sickness absence and yielded highly inconsistent results. Clinical interventions, psychological We found moderate quality evidence based on three studies that telephone or online cognitive behavioural therapy was more effective in reducing sick leave than usual primary or occupational care (SMD -0.23; 95% CI -0.45 to -0.01). Clinical interventions, psychological combined with antidepressant medication We found low quality evidence based on two studies that enhanced primary care did not substantially decrease sickness absence in the medium term (4 to 12 months) (SMD -0.02; 95% CI -0.15 to 0.12). A third study found no substantial effect on sickness absence in favour of this intervention in the long term (24 months). We found high quality evidence, based on one study, that a structured telephone outreach and care management program was more effective in reducing sickness absence than usual care (SMD -0.21; 95% CI -0.37 to -0.05). Clinical interventions, exercise We found low quality evidence based on one study that supervised strength exercise reduced sickness absence compared to relaxation (SMD -1.11; 95% CI -1.68 to -0.54). We found moderate quality evidence based on two studies that aerobic exercise was no more effective in reducing sickness absence than relaxation or stretching (SMD -0.06; 95% CI -0.36 to 0.24).

AUTHORS' CONCLUSIONS: We found moderate quality evidence that adding a work-directed intervention to a clinical intervention reduced the number of days on sick leave compared to a clinical intervention alone. We also found moderate quality evidence that enhancing primary or occupational care with cognitive behavioural therapy reduced sick leave compared to the usual care. A structured telephone outreach and care management program that included medication reduced sickness absence compared to usual care. However, enhancing primary care with a quality improvement program did not have a considerable effect on sickness absence. There was no evidence of a difference in effect on sickness absence of one antidepressant medication compared to another. More studies are needed on work-directed interventions. Clinical intervention studies should also include work outcomes to increase our knowledge on reducing sickness absence in depressed workers.

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References:

1. Nieuwenhuijsen K, Faber B, Verbeek JH, et al. Interventions to improve return to work in depressed people. *Cochrane Database Syst Rev.* 2014;12:CD006237.
2. Hogarth T, Hasluck C, Gambin L, Behle H, Li Y, Lyonette C. *Evaluation of employment advisers in the Improving Access to Psychological Therapies programme (RR826)* 2013.
3. Working for Wellness. *IAPT Employment Support Services in London: Assessment of the Economic Impact*
4. Gebert S. Psychological therapies : annual report on the use of IAPT services : England 2015-16.
5. Kinoshita Y, Furukawa TA, Kinoshita K, et al. Supported employment for adults with severe mental illness. *Cochrane Database Syst Rev.* 2013;9(CD008297).
6. Steadman K. [An evaluation of the "IPS in IAPT" psychological wellbeing and work feasibility pilot]. London: The Work Foundation; 2015.
7. Primary Care Research Group Peninsula College of Medicine and Dentistry. *The South West Improving Access to Psychological Therapies (IAPT) Evaluation Study* 2011.

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The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days. The briefing is in four parts:

- i. General context
- ii. The question in a research format
- iii. What the research evidence says
- iv. Alignment with PenCLAHRC research priority criteria

QUESTION: In intensive care units patients with severe sepsis, do steroids reduce mortality?

General context and definitions: Sepsis is a life-threatening condition that arises when the body's response to infection injures its own tissues and organs. *Severe sepsis* is diagnosed when sepsis is associated with organ failure. *Septic shock* occurs when severe sepsis is combined with a fall in systemic blood pressure that does not improve with intravenous fluids. The use of steroids in patients with severe sepsis continues despite inconclusive evidence regarding the benefits and harms of using them, in particular their impact on mortality.

Why might steroids help? The systemic response to sepsis includes activating pro-inflammatory pathways and cytokines with wide ranging effects on tissues. Corticosteroids can act to reduce these processes, suggesting a possible role for corticosteroid use. In addition, blood vessels' ability to maintain pressure within the cardiovascular system (vasomotor tone) decreases in septic shock, and corticosteroids can improve vascular function and therefore organ perfusion. Finally, a common feature of sepsis is reduced adrenal gland function. About 30% of all critically ill patients show adrenal insufficiency, and this rises to 50–60% in septic shock. The presence of adrenal insufficiency in septic shock patients has been associated with worse outcomes, including greater mortality and prolonged requirements for drugs to support blood pressure.

The question in a structured format: In considering this as a research question, we could frame it as:

<i>Population:</i>	Adults with severe sepsis or septic shock in intensive care
<i>Intervention:</i>	Steroid therapy (low dose/high dose)
<i>Comparator:</i>	No steroid/ Placebo
<i>Outcomes of Interest:</i>	Mortality Time to recovery Adverse events

What the research evidence says: There have been a number of systematic reviews investigating the effectiveness and safety of steroid therapy for sepsis in the past 10 years. The most recent, a Cochrane review by Annane et al [1], examined the effects of corticosteroids on death at one month in patients with sepsis, and whether dose and duration of corticosteroids influenced response. Corticosteroids reduced risk of death at 28 days by 13% (among 27 trials, 3176 participants). Both intensive care unit (ICU) and in-hospital deaths were reduced (13 and 17 trials, respectively).

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The review found that survival benefits were dependent on the dose of corticosteroids - the lower the dose (less than 400 mg of hydrocortisone or equivalent per day) for a longer duration of treatment (three or more days at the full dose) the better. Length of stay in intensive care was reduced by more than two days (10 trials). Corticosteroids did not cause harm, except for a mild increase in blood glucose and sodium levels. Gastrointestinal bleeding, infection and neuromuscular weakness were not increased.

In contrast to this, in the same year, Volbeda et al [2] reported on a systematic review and meta-analysis of 35 randomised controlled trials investigating corticosteroids for sepsis, severe sepsis and septic shock. These authors concluded there was no evidence of benefit, with regard to mortality, for either low dose or high dose corticosteroid treatment for patients with sepsis. They did not report on intensive care specific studies. Differences in the conclusions between the two reviews may be explained by different 'included' studies, as well as the timing of the primary outcome (mortality at one month versus mortality at longest follow-up). Volbeda et al also concluded from their review and trial sequential analysis that "more than 17,000 patients would need to be randomised before firm conclusions could be drawn on any present or absent effect of steroid intervention with a 10% relative risk reduction".

A systematic review (and position statement) from the American Academy of Emergency Medicine [3] on the effectiveness of low dose steroids for septic shock concluded (from seven studies) that while low-dose corticosteroids may reverse shock faster, 28 day mortality was not improved. Minneci et al [4], in their review of 21 studies, concluded that the effects of steroids in sepsis are dependent on both steroid dose and severity of illness. They found that high-dose steroids during sepsis increased mortality, whereas the effects of low-dose steroids on mortality appeared to be dependent on severity of illness, with low-dose steroids decreasing mortality in more severely ill patients. Low-dose steroids also improved shock reversal during sepsis, independently of severity of illness. In both reviews above however, intensive care populations were not separated as a sub-group.

Most recently, a review of reviews [5] found 14 systematic reviews on this topic, covering 53 randomised controlled trials. The authors concluded that the use of corticosteroids during a sepsis episode *probably* favours reversal of shock, briefly shortens the stay in intensive care unit and might reduce mortality, with few clinically relevant adverse effects. This review included studies with varied definitions of sepsis, different presenting populations and a wide range of steroid interventions and primary outcomes.

Across all the reviews cited above, authors suggest there is a need for further research and evidence in the following areas: the optimal timing for starting treatment, whether treatment should be continuous or intermittent, the optimal dose of corticosteroid treatment, the duration and modality of withdrawal of treatment, and optimal treatments for populations with different infections. A selection of primary research studies addressing some of these uncertainties is included in the *relevant abstracts* section at the end of this briefing [6-8].

Ongoing studies/ Trials in progress: No ongoing trials were located.

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: In 2015, across the UK it was estimated that there were about 147,000 cases of sepsis per year, with an associated 47,000 deaths [9]. More globally, the current incidence of sepsis in industrialized countries ranges from 50 to 100 cases per 100,000 population, with short-term mortality of 20% to 50% [1]. People usually die from hypotension or from progressive multiple organ failure [1]. Older adults and those with pre-existing chronic health conditions are more vulnerable to infections leading to sepsis.

The potential for health improvement: Patients with sepsis have prolonged hospital stay and often require critical care input. In the UK, sepsis consumes 30% of critical care expenditure and it is estimated to cost £20,000 to treat each patient [10]. It has been estimated that treating sepsis costs the UK over £2 billion per year [9]. At a national level, the spotlight on sepsis as a key source of avoidable mortality and morbidity has been intensifying. The 2015 NCEPOD (National Confidential Enquiry into Patient Outcome and Death) [11] reported that there was room for improvement in the management of 2 in every 3 patients with sepsis, and that only a third of the patients they reviewed received good quality care. The UK Sepsis Trust [9] has estimated that a typical medium-sized general hospital could save £1.25 million annually through improved management of sepsis, and that achieving 80% delivery of the basic standards of care is likely to save 10,000 lives per year and around £170 million annually for the National Health Service. The longer term fiscal cost, contributed to by reduced productivity in survivors and victims, is not known.

The practicality of the research question: Any potential research would likely benefit from the South West Critical Care Network (SWCCN). The SWCCN was re-established in 2014 as a set of regionally based collaborative partnerships, enabling clinical services to work together to promote the highest quality critical care services for the regions. The main focus of the network is adult critical care.

Whether the South West is a good place to do this research: Sepsis is an important cause of morbidity and mortality in the older population. As the population becomes increasingly old, this subset of the population will be admitted more frequently into ICUs and their management may pose an increasing challenge to the treating intensivists. The South West Peninsula has an older population than the England average. Latest estimates from 2014 suggest there were over 1.14 million people aged over 65 living in the South West, of which 165,000 are aged over 85, a third of which are aged over 90. It is estimated that by 2025, there will be a 25% increase in people aged over 65, and a 50% increase in those aged over 90.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

National Institute for Health and Care Excellence. NICE Guideline [NG51] Sepsis: recognition, diagnosis and management (Published July 2016)

NHS England. Improving outcomes for patients with sepsis: a cross-system action plan. December 2015

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Dellinger, RP et al. Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012. *Critical Care Medicine* 41(2). 2013

Irish National Clinical Effectiveness Committee (2014) Sepsis Management. National Clinical Guideline (Ireland) No. 6. Available from: <http://www.hse.ie/eng/about/Who/clinical/natclinprog/sepsis/>

Relevant Abstracts:

2012 B. Casserly, H. Gerlach, G. S. Phillips, S. Lemeshow, J. C. Marshall, T. M. Osborn and M. M. Levy; Low-dose steroids in adult septic shock: results of the Surviving Sepsis Campaign. *Intensive care medicine*, 38, 1946-54

OBJECTIVE: The Surviving Sepsis Campaign (SSC) developed guidelines and treatment bundles for the administration of steroids in adult septic shock. However, it is not clear how this has affected clinical practice or patient outcome. **DESIGN AND SETTING:** The SSC has developed an extensive database to assess the overall effect of its guidelines on clinical practice and patient outcome. This analysis focuses on one particular element of the SSC's management bundle, namely, the administration of low-dose steroids in adult septic shock. This analysis was conducted on data submitted from January 2005 through March 2010 including 27,836 subjects at 218 sites. **MAIN RESULTS:** A total of 17,847 (of the total 27,836) patients in the database required vasopressor therapy despite fluid resuscitation and therefore met the eligibility criteria for receiving low-dose steroids. A total of 8,992 patients (50.4 %) received low-dose steroids for their septic shock. Patients in Europe (59.4 %) and South America (51.9 %) were more likely to be prescribed low-dose steroids compared to their counterparts in North America (46.2 %, $p < 0.001$). The adjusted hospital mortality was significantly higher (OR 1.18, 95 % CI 1.09-1.23, $p < 0.001$) in patients who received low-dose steroids compared to those who did not. There was still an association with increased adjusted hospital mortality with low-dose steroids even if they were prescribed within 8 h (OR 1.23, 95 % CI 1.13-1.34, $p < 0.001$). **CONCLUSIONS:** Steroids were commonly administered in the treatment of septic shock in this subset analysis of the Surviving Sepsis Campaign database. However, this was associated with an increase in adjusted hospital mortality.

2015 Z. Chen, C. Yang, H. He and Z. He; The impacts of low-dose corticosteroids infusion given in different manners on refractory septic shock patients. *Chinese Critical Care Medicine*, 27, 443-7

Objective: To discuss the influence of different ways of low-dose corticosteroids infusion on hemodynamics, changes in blood glucose level and prognosis in patients with refractory septic shock. **Methods:** A prospective single-blind randomized controlled trial was conducted. Refractory septic shock patients admitted to the Department of Critical Care Medicine of Jiangxi Provincial People's Hospital from April 1st, 2013 to October 31st, 2014 were enrolled for the study. The patients were divided into control group and research group by random number table. Besides conventional treatment for septic shock, patients in control group were given 200 mg/d hydrocortisone intravenous infusion lasting for 2 hours, while those of research group were given 8.33 mg/h hydrocortisone per hour with an intravenous pump. Treatment lasted for 5 continuous days for both groups. The changes in heart rate (HR), mean arterial pressure (MAP), central venous pressure (CVP) and arterial blood lactic acid in both groups were observed at the time of enrolment and 6 hours, 24 hours, 48 hours, and 5 days after the treatment. With a dynamic blood glucose monitor, mean blood glucose (MBG) level, largest amplitude of glycemic excursions (LAGE), glucose variability (GV), and the ratio of hyperglycaemia time were recorded. The duration of shock, length of intensive care unit (ICU) stay, total length of hospital stay, and 28-day mortality of both groups were recorded. **Results:** Seventy-nine septic shock patients were assigned to the treatment, with 41 in control group, and 38 in research group. Compared with control group, 6-hour MAP in research group was obviously lowered [mmHg (1 mmHg = 0.133 kPa): 66.31+/-

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4.38 vs. 68.58 \pm 4.86, $t = 1.062$, $P = 0.033$], but there were no significant differences in HR, MAP, CVP, lactic acid clearance and norepinephrine (NE) utilization rates at other time points between two groups. No significant difference in MBG was found between research group and control group (mmol/L: 8.69 \pm 2.14 vs. 9.95 \pm 3.87, $t = 1.771$, $P = 0.080$), but LAGE, GV, the ratio of hyperglycemia time in research group were significantly lower than those of the control group [LAGE (mmol/L): 17.18 \pm 8.97 vs. 22.71 \pm 11.80, $t = 2.331$, $P = 0.022$; GV (mmol/L): 2.57 \pm 1.05 vs. 3.16 \pm 1.37, $t = 2.136$, $P = 0.036$; the ratio of hyperglycemia time: (43.1 \pm 11.7) % vs. (49.4 \pm 15.3) %, $t = 2.044$, $P = 0.044$]. There was no statistical difference in the following features between research group and control group, such as the duration of shock (days: 3.47 \pm 0.98 vs. 3.61 \pm 1.07, $t = 0.605$, $P = 0.547$), length of ICU stay (days: 8.74 \pm 3.12 vs. 9.97 \pm 3.37, $t = 1.543$, $P = 0.120$), total length of hospital stay (days: 18.34 \pm 9.27 vs. 19.58 \pm 9.83, $t = 0.576$, $P = 0.566$) and 28-day mortality rate (23.68% vs. 26.83%, $\chi^2 = 0.103$, $P = 0.748$). Conclusions: Compared with slow intravenous infusion, a continuous intravenous supplementation of small amount of hydrocortisone to patients with refractory septic shock could stabilize blood glucose levels and maintain metabolic balance efficiently. However, in both groups there was no significant difference in the efficiency in stabilizing hemodynamics, shortening shock duration, reducing ICU or hospital days and decreasing 28-day mortality.

2014 L. Mirea, R. Ungureanu, D. Pavelescu, I. C. Grintescu, C. Dumitrache, I. Grintescu and D. Mirea; Continuous administration of corticosteroids in septic shock can reduce risk of hypernatremia. Critical care (London, England), 18, S86

Introduction Although the administration of hydrocortisone in septic shock generates adverse effects, the risk of corticosteroid-induced hypernatremia may be reduced by continuous administration of the drug [1,2]. **Methods** A total of 171 patients with septic shock were randomized into three study groups: group A (n = 58), 200 mg/day hydrocortisone hemisuccinate in four doses; group B (n = 59), same dose of hydrocortisone hemisuccinate in continuous administration; group C (n = 54), no hydrocortisone hemisuccinate. Mean serum sodium values, the number of hypernatremia episodes and variations in serum sodium (Na var) were investigated for 7 days. The local ethics committee approved the study. **Results** There were no differences between the three groups at the beginning of the study regarding demographic data and the clinical characteristics. Mean values of natraemia were normal in group C (140.35 \pm 7.390 mEq/l to 144.79 \pm 8.338 mEq/l) during the study period. High mean values appeared on day 4 in group A (147.21 \pm 8.470 mEq/l to 149.37 \pm 8.973 mEq/l on day 7) and on day 5 in group B (146.36 \pm 8.272 mEq/l to 147.70 \pm 8.865 mEq/l). Na var was 8.59 \pm 5.960 mEq/l (-8 and 21 mEq/l) in group A, 6.63 \pm 7.609 mEq/l (-17 and 23 mEq/l) in group B and 4.54 \pm 7.455 mEq/l (-12 and 22 mEq/l) in group C. This variation is statistically significant when groups A and B are compared with group C ($P = 0.012$) and when only group A is compared with group C ($P = 0.0019$). The risk of hypernatremia after hydrocortisone hemisuccinate was almost three times higher than that of patients who did not receive this drug (RR 2.82, 1.35 <OR <5.90, $P = 0.0041$) and slightly higher when HHS was delivered as a bolus (RR 3.08, 1.32 <OR <7.25, $P = 0.0071$). **Conclusion** Continuous administration of hydrocortisone hemisuccinate in septic shock is associated with a lower risk of hypernatremia than bolus administration.

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The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days. The briefing is in four parts:

- i. General context
- ii. The question in a research format
- iii. What the research evidence says
- iv. Alignment with PenCLAHRC research priority criteria

QUESTION: Is social prescribing effective for treating prescription drug misuse?

General context and definitions:

Social prescribing or ‘community referral’ is a means of enabling primary care services to refer patients with social, emotional or practical needs to a range of local, non-clinical services. It provides GPs with a non-medical referral option that can operate alongside existing treatments to improve health and well-being. While there is no widely agreed definition of social prescribing, or ‘community referrals’, reports on social prescribing include an extensive range of prescribed interventions and activities(1), for example, social prescribing may include exercise, nature and art-based interventions.

Prescription drug abuse/misuse refers to the use of prescription medications for other purposes or in ways other than prescribed. This includes taking someone else’s prescription medications to relieve pain, increasing the dose of prescribed medications without medical approval and use of prescribed medications as alternatives to illegal drugs (<http://www.sspd.org.uk/>).

The question in a structured format: In considering this as a research question, we could frame it as:

<i>Population:</i>	Adults with prescribed medication who are (or are highlighted as at risk of) misusing their medication.
<i>Intervention:</i>	Social Prescribing (community referral) - where primary care can refer people with social, emotional or practical needs to non-clinical services such as exercise, nature, art or other socially based interventions as appropriate
<i>Comparator:</i>	Standard care with no social prescribing.
<i>Outcomes of Interest:</i>	Patient outcomes – levels of medication misuse, quality of life and mental health, levels of social, emotional or practical needs. Resource use.

What the research evidence says:

There are several published systematic reviews on areas related to this topic. However, the evidence for particular social prescribing is scarce and in particular its use for reducing prescription drug misuse. A recent rapid (non-systematic) review(2) was conducted on the use of social prescribing in general and reported that the UK is at the forefront of research. There are several comprehensive reviews of

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prescription exercise (exercise referral systems) which would account for one potential form of social prescribing though the effect in reducing prescription drug misuse has not been recorded.

A number of social prescribing schemes exist around the UK but few have been formally evaluated. Schemes are not generally aimed at prescription drug misuse and this is not currently an explicit outcome of interest in the existing schemes and pilots.

Ongoing studies/ Trials in progress:

A review looking at 'how' and in 'what context' social prescribing can be implemented is already underway by PenCLAHRC.

How does this fit with PenCLAHRC research priority criteria?

Size of the health problem: The cost of medicines in 2013, including costs for use in hospitals, was more than £15 billion. More than 1 billion prescription items were dispensed in the community in England, an average of 2.7 million items every day. The gross annual cost of NHS primary and community care prescription medicines wastage in England is thought to be in the order of £300 million per year (approx. 2% of the cost of medicines) of which a part may be due to prescription drug misuse. A crude estimate of the costs associated with medicines "wastage" through misuse suggests an upper limit of 16.5% of wasted drugs or £3million per year in the Southwest. Despite the potentially serious complications and the risk of addiction, prescription drug abuse tends to be on the rise. (<http://www.sspd.org.uk/>). As an indicator of the potential size of the problem using one area of prescribing, in 2013 over 53m prescriptions were issued in the community for antidepressants, a 6% increase on the previous year, a 92% increase since 2003 yet the prevalence of depression has not risen since 2003. However, prescription numbers are increasing because more patients are taking antidepressants for longer which may not always be appropriate(4).

The potential for health improvement: Prescription drug misuse is observed in all age groups. There is potential for social prescribing to lead to reduced prescription drug use and misuse through improving social and mental health outcomes in those affected and reduce costs to the society and the NHS. It is likely the social prescribing may also have longer term benefits and benefits beyond those we might currently recognise, but research to support this has not yet been conducted.

The practicality of the research question: A BBC documentary recently showed patients replacing prescribed pain killers and anti-depressant with exercise – however these people were not necessarily misusing their prescription medication. Social prescribing offers a sustainable way to engage people in physical activity generally but it has not yet been used for this target population. Primary research to evaluate the effectiveness of social prescribing to reduce prescription drug misuse is needed, alongside other potential positive benefits of reducing prescribing while achieving valued outcomes of treatment.

Whether the South West is a good place to do this research: Prescription drug misuse has major health and social implications and is reportedly particularly prevalent in the South West. Whilst often treated with counselling or drug based approaches, social prescribing could help in addressing prescription drug misuse by diverting attention, building confidence or improving mood. This topic will build on existing work happening in the South West with particular interest from the Plymouth Public Health team.

Alignment with local health priorities: This will be different across the South West region and between organisations. Please consider the briefing in line with your local priorities.

GUIDELINES & GOVERNMENT STRATEGIES relating to this area:

An evidence report to inform the commissioning of social prescribing conducted by the Centre for Research and Dissemination in 2015 states:

‘There is currently little evidence of effectiveness that could inform commissioning of a social prescribing programme. Current evidence tends to briefly describe the evaluation of small scale pilot projects but fails to provide sufficient detail to judge either success or value for money. Given the lack of evidence, consideration needs to be given to the evaluation of new schemes. If we are to improve existing knowledge, these should be comparative by design and seek to address when, for whom and how well does the scheme work? What effects does it have? What does it cost? Rigorous conduct and transparent reporting are essential.’(1)

Relevant Abstracts:

2016 A. Jensen, T. Stickley, W. Torrissen and K. Stigmar; Arts on prescription in Scandinavia: a review of current practice and future possibilities, *Perspectives in public health*

AIMS: This article reviews current practice relating to arts and culture on prescription in Sweden, Norway, Denmark and in the United Kingdom. It considers future possibilities and also each of the Scandinavian countries from a culture and health policy and research perspective. The United Kingdom perhaps leads the field of Arts on Prescription practice, and subsequent research is described in order to help identify what the Scandinavian countries might learn from the UK research.,

METHOD: The method adopted for the literature search was a rapid review which included peer-reviewed and grey literature in English and the respective languages of Scandinavia.,

RESULTS: The discussion considers the evidence to support social prescription and the potential obstacles of the implementation of Arts on Prescription in Scandinavian countries.,

CONCLUSION: The article concludes that of the Scandinavian countries, Sweden is ahead in terms of Arts on Prescription and has embraced the use of culture for health benefits on a different scale compared to Norway and Denmark. Denmark, in particular, is behind in recognising ways in which art and culture can benefit patients and for wider public health promotion. All three countries may benefit from the evidence provided by UK researchers.

2011 T. Pavey, N. Anokye, A. Taylor, P. Trueman, T. Moxham, K. Fox, M. Hillsdon, C. Green, J. Campbell, C. Foster, N. Mutrie, J. Searle and R. Taylor; The clinical effectiveness and cost-effectiveness of exercise referral schemes: a systematic review and economic evaluation, *Health Technology Assessment*

BACKGROUND: Exercise referral schemes (ERS) aim to identify inactive adults in the primary-care setting. The GP or health-care professional then refers the patient to a third-party service, with this service taking responsibility for prescribing and monitoring an exercise programme tailored to the needs of the individual.

OBJECTIVE: To assess the clinical effectiveness and cost-effectiveness of ERS for people with a diagnosed medical condition known to benefit from physical activity (PA). The scope of this report was broadened to consider individuals without a diagnosed condition who are sedentary. DATA SOURCES:

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MEDLINE; EMBASE; PsycINFO; The Cochrane Library, ISI Web of Science; SPORTDiscus and ongoing trial registries were searched (from 1990 to October 2009) and included study references were checked.

METHODS: Systematic reviews: the effectiveness of ERS, predictors of ERS uptake and adherence, and the cost-effectiveness of ERS; and the development of a decision-analytic economic model to assess cost-effectiveness of ERS.

RESULTS: Seven randomised controlled trials (UK, n = 5; non-UK, n = 2) met the effectiveness inclusion criteria, five comparing ERS with usual care, two compared ERS with an alternative PA intervention, and one to an ERS plus a self-determination theory (SDT) intervention. In intention-to-treat analysis, compared with usual care, there was weak evidence of an increase in the number of ERS participants who achieved a self-reported 90-150 minutes of at least moderate-intensity PA per week at 6-12 months' follow-up [pooled relative risk (RR) 1.11, 95% confidence interval 0.99 to 1.25]. There was no consistent evidence of a difference between ERS and usual care in the duration of moderate/vigorous intensity and total PA or other outcomes, for example physical fitness, serum lipids, health-related quality of life (HRQoL). There was no between-group difference in outcomes between ERS and alternative PA interventions or ERS plus a SDT intervention. None of the included trials separately reported outcomes in individuals with medical diagnoses. Fourteen observational studies and five randomised controlled trials provided a numerical assessment of ERS uptake and adherence (UK, n = 16; non-UK, n = 3). Women and older people were more likely to take up ERS but women, when compared with men, were less likely to adhere. The four previous economic evaluations identified suggest ERS to be a cost-effective intervention. Indicative incremental cost per quality-adjusted life-year (QALY) estimates for ERS for various scenarios were based on a de novo model-based economic evaluation. Compared with usual care, the mean incremental cost for ERS was £169 and the mean incremental QALY was 0.008, with the base-case incremental cost-effectiveness ratio at £20,876 per QALY in sedentary people without a medical condition and a cost per QALY of £14,618 in sedentary obese individuals, £12,834 in sedentary hypertensive patients, and £8414 for sedentary individuals with depression. Estimates of cost-effectiveness were highly sensitive to plausible variations in the RR for change in PA and cost of ERS.

LIMITATIONS: We found very limited evidence of the effectiveness of ERS. The estimates of the cost-effectiveness of ERS are based on a simple analytical framework. The economic evaluation reports small differences in costs and effects, and findings highlight the wide range of uncertainty associated with the estimates of effectiveness and the impact of effectiveness on HRQoL. No data were identified as part of the effectiveness review to allow for adjustment of the effect of ERS in different populations.

CONCLUSIONS: There remains considerable uncertainty as to the effectiveness of ERS for increasing activity, fitness or health indicators or whether they are an efficient use of resources in sedentary people without a medical diagnosis. We failed to identify any trial-based evidence of the effectiveness of ERS in those with a medical diagnosis. Future work should include randomised controlled trials assessing the clinical effectiveness and cost-effectiveness of ERS in disease groups that may benefit from PA.

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